Patient education in the management of coronary heart disease

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Patient education in the management of coronary heart disease (Review)

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[Intervention Review]

Patient education in the management of coronary heart disease

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ABSTRACT

Background

Coronary heart disease (CHD) is the single most common cause of death globally. However, with falling CHD mortality rates, an increasing number of people live with CHD and may need support to manage their symptoms and improve prognosis. Cardiac rehabilitation is a complex multifaceted intervention which aims to improve the health outcomes of people with CHD. Cardiac rehabilitation consists of three core modalities: education, exercise training and psychological support. This is an update of a Cochrane systematic review previously published in 2011, which aims to investigate the specific impact of the educational component of cardiac rehabilitation.

Objectives

1. To assess the effects of patient education delivered as part of cardiac rehabilitation, compared with usual care on mortality, morbidity, health-related quality of life (HRQoL) and healthcare costs in patients with CHD.

2. To explore the potential study level predictors of the effects of patient education in patients with CHD (e.g. individual versus group intervention, timing with respect to index cardiac event).

Search methods

We updated searches from the previous Cochrane review, by searching the Cochrane Central Register of Controlled Trials (CENTRAL) (Cochrane Library, Issue 6, 2016), MEDLINE (Ovid), Embase (Ovid), PsycINFO (Ovid) and CINAHL (EBSCO) in June 2016. Three trials registries, previous systematic reviews and reference lists of included studies were also searched. No language restrictions were applied.

Selection criteria

1. Randomised controlled trials (RCTs) where the primary interventional intent was education delivered as part of cardiac rehabilitation.

2. Studies with a minimum of six-months follow-up and published in 1990 or later.

3. Adults with a diagnosis of CHD.

Data collection and analysis

Two review authors independently screened all identified references for inclusion based on the above inclusion criteria. One author extracted study characteristics from the included trials and assessed their risk of bias; a second review author checked data. Two independent reviewers extracted outcome data onto a standardised collection form. For dichotomous variables, risk ratios and 95% confidence intervals (CI) were derived for each outcome. Heterogeneity amongst included studies was explored qualitatively and quantitatively. Where appropriate and possible, results from included studies were combined for each outcome to give an overall estimate of treatment effect. Given the degree of clinical heterogeneity seen in participant selection, interventions and comparators across studies, we decided it was appropriate to pool studies using random-effects modelling. We planned to undertake subgroup analysis and stratified meta-analysis, sensitivity analysis and meta-regression to examine potential treatment effect modifiers. We used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to evaluate the quality of the evidence and the GRADE profiler (GRADEpro GDT) to create summary of findings tables.

Main results

This updated review included a total of 22 trials which randomised 76,864 people with CHD to an education intervention or a 'no education' comparator. Nine new trials (8215 people) were included for this update. We judged most included studies as low risk of bias across most domains. Educational 'dose' ranged from one 40 minute face-to-face session plus a 15 minute follow-up call, to a four-week residential stay with 11 months of follow-up sessions. Control groups received usual medical care, typically consisting of referral to an outpatient cardiologist, primary care physician, or both.

We found evidence of no difference in effect of education-based interventions on total mortality (13 studies, 10,075 participants; 189/5187 (3.6%) versus 222/4888 (4.6%); random effects risk ratio (RR) 0.80, 95% CI 0.60 to 1.05; moderate quality evidence). Individual causes of mortality were reported rarely, and we were unable to report separate results for cardiovascular mortality or non-cardiovascular mortality. There was evidence of no difference in effect of education-based interventions on fatal and/or non fatal myocardial infarction (MI) (2 studies, 209 participants; 7/107 (6.5%) versus 12/102 (11.8%); random effects RR 0.63, 95% CI 0.26 to 1.48; very low quality of evidence). However, there was some evidence of a reduction with education in fatal and/or non-fatal cardiovascular events (2 studies, 310 studies; 21/152 (13.8%) versus 61/158 (38.6%); random effects RR 0.36, 95% CI 0.23 to 0.56; low quality evidence). There was evidence of no difference in effect of education on the rate of total revascularisations (3 studies, 456 participants; 5/228 (2.2%) versus 8/228 (3.5%); random effects RR 0.58, 95% CI 0.19 to 1.71; very low quality evidence) or hospitalisations (5 studies, 14,849 participants; 656/10048 (6.5%) versus 381/4801 (7.9%); random effects RR 0.93, 95% CI 0.71 to 1.21; very low quality evidence). There was evidence of no difference between groups for all cause withdrawal (17 studies, 10,972 participants; 525/5632 (9.3%) versus 493/5340 (9.2%); random effects RR 1.04, 95% CI 0.88 to 1.22; low quality evidence). Although some health-related quality of life (HRQoL) domain scores were higher with education, there was no consistent evidence of superiority across all domains.

Authors' conclusions

We found no reduction in total mortality, in people who received education delivered as part of cardiac rehabilitation, compared to people in control groups (moderate quality evidence). There were no improvements in fatal or non fatal MI, total revascularisations or hospitalisations, with education. There was some evidence of a reduction in fatal and/or non-fatal cardiovascular events with education, but this was based on only two studies. There was also some evidence to suggest that education-based interventions may improve HRQoL. Our findings are supportive of current national and international clinical guidelines that cardiac rehabilitation for people with CHD should be comprehensive and include educational interventions together with exercise and psychological therapy. Further definitive research into education interventions for people with CHD is needed.

PLAIN LANGUAGE SUMMARY

Education for people with coronary heart disease

Review question

What are the effects of patient education delivered as part of cardiac rehabilitation, compared with usual care on mortality, morbidity, health-related quality of life (HRQoL) and healthcare costs in patients with coronary heart disease (CHD)?

Background

Coronary heart disease (CHD) is the single most common cause of death globally. However, more people now live with heart disease and may need support to manage symptoms and reduce risk of future problems such as heart attacks. Education is a common element of cardiac rehabilitation, which aims to improve the health and outcomes of people with heart disease. This is an update of a review last published in 2011.

Search date

We searched up to June 2016.

Study characteristics

We searched the scientific literature for randomised controlled trials (experiments that randomly allocate participants to one of two or more treatment groups) looking at the effectiveness of education-based treatments compared with no education in people of all ages with CHD.

We included nine new trials which involved 8215 people with coronary heart disease that compared patient education with no education. We included a total of 22 trials that studied 76,864 people with heart disease, most of whom had survived heart attack, and had undergone heart bypass surgery or angioplasty (a procedure which opens blocked vessels that supply blood to heart muscle).

Study funding sources

Sixteen studies reported sources of funding; six did not report funding sources. One study was funded by an industrial sponsor, four by health insurance companies and 11 by government or public sources.

Key results

Findings of this update are similar to the last review version (2011). Patient education, as part of a cardiac rehabilitation programme, does not contribute to fewer deaths, further heart attacks, heart by-pass or angioplasty, or admission to hospital for heart-related problems. There is some evidence of fewer other heart-related events and improvements in health-related quality of life with education-based interventions. Individual causes of death were not reported, so we were unable to determine how many people in the studies died from heart-related causes or other causes of death.

Although there is insufficient information at present to fully understand the benefits or harms of patient education for people with heart disease, our findings broadly support current guidelines that people with heart disease should receive comprehensive rehabilitation that includes education. Further research is needed to evaluate the most clinically and cost-effective ways of providing education for people with heart disease.

Quality of evidence

Overall, evidence was assessed as very low to moderate quality.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

Patient education for the management of coronary heart disease

Patient or population: patients with coronary heart disease
Settings: Centre or home-based
Intervention: Patient education

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Patient education				
Total mortality at the end of the follow-up period No of deaths Follow-up: median 18 months	**Study population**		**RR 0.80** (0.60 to 1.05)	10075 (13 studies)	⊕⊕⊕◯ **Moderate**[1]	
	46 per 1000	**37 per 1000** (28 to 48)				
	Moderate population					
	43 per 1000	**34 per 1000** (26 to 45)				
Fatal and/or non-fatal MI at the end of the follow up period Follow-up: median 33 months	**Study population**		**RR 0.63** (0.26 to 1.48)	209 (2 studies)	⊕◯◯◯ **very low**[2,3,4]	
	118 per 1000	**74 per 1000** (31 to 174)				
	Moderate population					
	106 per 1000	**67 per 1000** (28 to 157)				

Other fatal and/or non-fatal cardiovascular events Follow-up: median 21 months	**Study population**		**RR 0.36** (0.23 to 0.56)	310 (2 studies)	⊕⊕◯◯ **low**[2,4]
	386 per 1000	**139 per 1000** (89 to 216)			
	Moderate population				
	324 per 1000	**117 per 1000** (75 to 181)			
Total revascularisations (including CABG and PCI) Follow-up: median 36 months	**Study population**		**RR 0.58** (0.19 to 1.71)	456 (3 studies)	⊕◯◯◯ **very low**[2,3,4]
	35 per 1000	**20 per 1000** (7 to 60)			
	Moderate population				
	33 per 1000	**19 per 1000** (6 to 56)			
Hospitalisations (cardiac-related) at end of follow up period Follow-up: median 12 months	**Study population**		**RR 0.93** (0.71 to 1.21)	14849 (5 studies)	⊕◯◯◯ **very low**[1,2,5]
	79 per 1000	**74 per 1000** (56 to 96)			
	Moderate population				
	141 per 1000	**131 per 1000** (100 to 171)			
All cause withdrawal at follow-up Follow-up: median 12 months	**Study population**		**RR 1.04** (0.88 to 1.22)	10972 (17 studies)	⊕⊕◯◯ **low**[2,6,7]
	92 per 1000	**96 per 1000** (81 to 113)			
	Moderate population				

	70 per 1000	**73 per 1000** (62 to 85)				
HRQoL Various HRQoL measures Follow-up: median 12 months	Not measurable	Not measurable	Not measurable	4393 (13 studies)	⊕⊕⊕◯ **moderate**[2]	HRQoL in intervention > HRQoL in comparator, in then 9/99 domains

[1] 95% CIs include both no effect and appreciable benefit (i.e. CI < 0.75)

[2] Blinding of outcome assessors was poorly described in over 50% of included studies; bias likely

[3] 95% CIs include both no effect, appreciate benefit and appreciable harm (i.e. CI < 0.75 and > 1.25)

[4] The point estimate is likely to be imprecise due to very low event rates

[5] I^2 > 40%; heterogeneity may be important

[6] 95% CIs include both no effect and appreciate harm (i.e. CI > 1.25)

[7] Evidence of funnel plot asymmetry therefore publication bias likely

BACKGROUND

Description of the condition

Coronary heart disease (CHD) is the largest cause of death globally. In 2105, an estimated 8,8 million people died from CHD worldwide (WHO 2017). In the United Kingdom (UK), an estimated 2.3 million people live with CHD, and in 2014, the condition accounted for around 69,000 deaths (15% of male deaths and 10% of female deaths), and 3.4% of all inpatient episodes in men and 1.4% in women (BHF 2015). Most cardiovascular diseases can be prevented by addressing behavioural risk factors such as smoking, unhealthy diet and obesity, physical inactivity and harmful use of alcohol. Indeed, through early detection strategies, advanced medical treatment, lifestyle changes and risk factor reductions, UK age-standardised CHD death rates declined by 73% for all ages, and 81% for those dying before the age of 75, between 1974 and 2013 (BHF 2015). Nonetheless, with falling CHD mortality rates, an increasing number of people live with CHD and may need support to manage their symptoms and improve prognosis.

Description of the intervention

Based on evidence from previous meta-analyses and systematic reviews, exercise-based cardiac rehabilitation following a cardiac event is a Class I recommendation from the American College of Cardiology/American Heart Association (Balady 2011; Kulik 2015) and the European Society of Cardiology (ESC 2012; ESC 2016; Smith 2011). Many definitions of cardiac rehabilitation have been proposed. The following definition encompasses the key concepts of cardiac rehabilitation: "The coordinated sum of activities required to influence favourably the underlying cause of cardiovascular disease, as well as to provide the best possible physical, mental and social conditions, so that the patients may, by their own efforts, preserve or resume optimal functioning in their community and through improved health behaviour, slow or reverse progression of disease" (BACPR 2012). Cardiac rehabilitation is a complex intervention that may involve a variety of therapies, including exercise, risk factor education, behaviour change, psychological support, and strategies that are aimed at targeting traditional risk factors for cardiovascular disease. Cardiac rehabilitation is an essential part of contemporary heart disease care and is considered a priority in countries with a high prevalence of CHD.
Patient education is defined as "the process by which health professionals and others impart information to patients that will alter their health behaviours or improve their health status" (Koongstvedt 2001). Self-management education programmes are designed to allow people with chronic conditions to take an active part in managing their own condition (Foster 2007). They are complex behavioural interventions which target patient education and promote self-care behaviour and risk-factor modification and aim to improve health outcomes and decrease the incidence of complications for patients by supporting, not replacing, medical care (Walker 2003). This in turn may lead to reduced hospitalisations and medical appointments and an associated reduction in costs, both to the patient and the healthcare system (Ferri 2007). Educational interventions within cardiac care increase patients' knowledge and facilitate behaviour change (Ghisi 2014). Educational interventions in cardiac care have been shown to increase physical activity, and lead to healthier dietary habits and smoking cessation, although any related improvement in response to cardiac symptoms, medication compliance or psychosocial well-being is more equivocal (Ghisi 2014).
The delivery of patient education programmes can vary substantially, and may be classroom- or home-based, group or individual, tailored or generic. Common topics include nutrition, exercise, risk factor modification, psychosocial well-being, and medications (Ghisi 2014). Duration, frequency and ongoing maintenance or re-inforcement also varies between programmes. Some programmes are developed according to validated educational theory and by trained professionals who are part of an interdisciplinary team, whilst others are delivered by peers. Some programmes may use adjunctive written materials or videotapes that supplement clinical consultations, while Internet- and mobile phone-based applications may be used to deliver educational material and messages to patients (Neubeck 2009). Telephone follow-up is increasingly used by healthcare providers to reach patients more frequently and in their own environment without the burden of a clinic visit (Phillips 2014).
Both the American College of Cardiology/American Heart Association and the European Society of Cardiology recognise education as an important component of comprehensive cardiac rehabilitation programmes and give a Class I recommendation that patients with non-ST-elevation acute coronary syndromes (ACS) and individuals with very high cardiovascular disease risk, should be educated about appropriate cholesterol management, blood pressure, smoking cessation, and lifestyle management (Amsterdam 2014; ESC 2016; Perk 2012). Exercise and psychological interventions are the subject of recent Cochrane systematic review updates (Anderson 2016; Richards 2017). Whilst these reviews have considered trials that have included education as a co-intervention, this review update specifically focuses on the impact of the educational component of cardiac rehabilitation for patients with CHD.

Why it is important to do this review

Two meta-analyses of education for people with CHD were published in the 1990s (Dusseldorp 1999; Mullen 1992). Mullen 1992 demonstrated a significant reduction in mortality associated with patient education (weighted average effect size 0.24 standard deviation units, 95% CI 0.14 to 0.33), which translated into a 19%

improvement in mortality. The average effects for morbidity (re-infarction and re-hospitalisation) were not found to be significant. However, one randomised controlled trial (RCT) was excluded from analysis because it was an outlier as it demonstrated a large positive effect size (Rahe 1979). Dusseldorp 1999 investigated the co-interventions of health education and stress management and concluded that these programmes yielded a mean reduction of 34% in cardiac mortality and a 29% reduction in re-infarction. A Cochrane Review was subsequently published in 2011 which identified 13 RCTs randomising a total of 68,556 participants (Brown 2011). Brown 2011 incorporated new evidence and addressed concerns relating to the generalisability of the results of the two earlier meta-analyses to the wider CHD population, and their applicability to policy formation, improved medical treatment of people with CHD, and the changing provision of cardiac rehabilitation services. Brown 2011 did not find evidence that education reduced total mortality, cardiac morbidity, revascularisation or hospitalisation compared to control, while there was some evidence to suggest that education may improve health-related quality of life (HRQoL) and reduce overall healthcare costs. A more recent systematic review investigated the impact of education on patients' knowledge and health behaviour change in people with CHD (Ghisi 2014), but to our knowledge, there have been no other recent meta-analyses which have updated the evidence on the effect of education delivered as part of cardiac rehabilitation, on mortality, morbidity and HRQoL in this population.

The American College of Cardiology/American Heart Association and the European Society of Cardiology recognise education as an important component of comprehensive cardiac rehabilitation programmes and give a Class I recommendation that people with non-ST-elevation ACS and those with very high cardiovascular disease risk should be educated about appropriate cholesterol management, blood pressure, smoking cessation, and lifestyle management (Amsterdam 2014; ESC 2016; Perk 2012).

This update aimed to use additional RCT evidence published since the 2011 Cochrane Review to re-assess the effectiveness of education compared with usual care on mortality, risk of hospital admission, myocardial infarction, revascularisation, HRQoL and healthcare costs in people with CHD.

OBJECTIVES

1. To assess the effects of patient education delivered as part of cardiac rehabilitation, compared with usual care on mortality, morbidity, health-related quality of life (HRQoL) and healthcare costs in patients with CHD.

2. To explore the potential study level predictors of the effects of patient education in patients with CHD (e.g. individual versus group intervention, timing with respect to index cardiac event).

METHODS

Criteria for considering studies for this review

Types of studies

To reflect contemporary coronary heart disease (CHD) practice we included randomised controlled trials (RCTs) published after 1990.

Types of participants

We included studies where participants were adults (aged ≥ 18 years):

- who had experienced a myocardial infarction (MI);
- who underwent revascularisation (coronary artery bypass grafting (CABG), percutaneous coronary intervention (PCI) or coronary artery stenting); or
- who had angina pectoris or CHD defined by angiography.

We excluded studies of education programmes which included participants who:

- had received heart valve surgery;
- suffered from heart failure;
- were heart transplantation recipients;
- were implanted with cardiac-resynchronisation therapy; or
- were implanted with defibrillators.

Types of interventions

We identified RCTs where patient education was the primary intention of the cardiac rehabilitation intervention with a follow-up period of at least six months. We excluded studies of cardiac rehabilitation where exercise or psychological intervention were the primary focus for investigation. These latter components of cardiac rehabilitation have been investigated in recently updated Cochrane Reviews of exercise-based cardiac rehabilitation (Anderson 2016) and psychological cardiac rehabilitation interventions for people with CHD (Richards 2017).

For the purposes of this review, patient education was defined as the following:

1. instructional activities organised in a systematic way involving personal direct contact between a health professional and CHD patients with or without significant others: e.g. spouse, family member;

2. delivered as an inpatient, or outpatient in a community-based intervention setting or programme;

3. included some form of structured knowledge transfer about CHD, its causes, treatments or methods of secondary prevention; and

4. delivered in a face-to-face format, in groups or on a one-to-one basis. We also included alternative interactive methods of

educational delivery such as 'telehealth' (telephone, e-mail, Internet and teleconference between educator and patient).
We included only study interventions that met all the above criteria.
We excluded general information provision, which is not organised in a systematic way (e.g. written guidance given to a patient on leaving the cardiac care unit or personal communication with a healthcare provider), which was considered to be usual care.
Given the multifaceted nature of cardiac rehabilitation we excluded studies where exercise and psychological therapies, or both, were provided and patient education was not stated to be a primary intervention.
We particularly sought studies designed to assess the independent effect of education (e.g. patient education plus usual care versus usual care alone; patient education, usual care and exercise versus usual care and exercise alone; patient education, usual care and psychological intervention versus usual care and psychological intervention alone).

Types of outcome measures

The aim of the review was to include studies that reported event data (e.g. mortality, cardiovascular events). We excluded studies that only measured alternative outcomes such as changes in smoking, diet, blood pressure or effect of education on patient knowledge. We elected not to include these alternative surrogate outcomes because we considered event rates to be more significant.

Primary outcomes

- Total mortality.
- Cardiovascular mortality.
- Non-cardiovascular mortality.
- Fatal and/or non-fatal myocardial infarction (MI).
- Other fatal and/or non-fatal cardiovascular events.

Secondary outcomes

- Total revascularisations (including coronary artery bypass grafting (CABG) and percutaneous coronary intervention (PCI)).
- Hospitalisations (total number of cardiac-related patient admissions in the follow-up period following the intervention).
- Withdrawals.
- Health-related quality of life (HRQoL, using validated measures e.g. Short Form Health Survey SF-36, Sickness Impact Profile, Nottingham Health Profile).
- Adverse events.
- Healthcare costs and cost-effectiveness.

We excluded any study that did not measure one or more of these outcomes.

Search methods for identification of studies

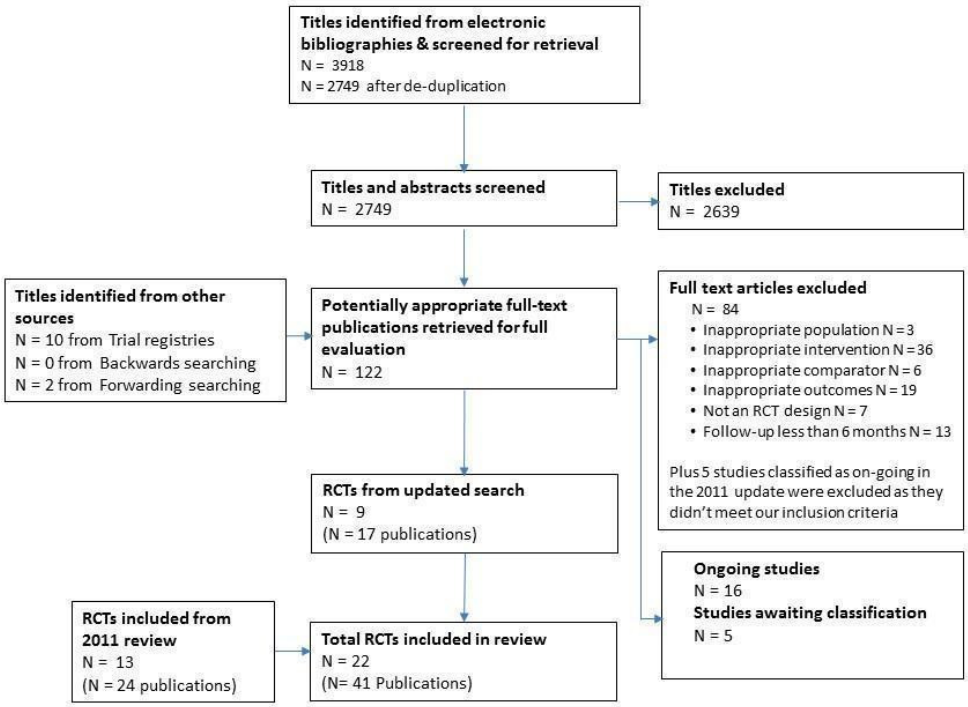
Electronic searches

We searched the following databases on 30 June 2016:
- CENTRAL Issue 6, 2016 (in the Cochrane Library);
- MEDLINE (Ovid) 1946 to June week 3 2016;
- Embase (Ovid) 1980 to 2016 week 26;
- PsycINFO (Ovid) 1806 to June week 3 2016; and
- CINAHL (EBSCO) 1937 to 30 June 2016.

The search strategies were designed with reference to those used previously (Brown 2011). We searched the databases using a strategy combining selected MeSH terms and free text terms relating to patient education and CHD, with filters applied to limit to RCTs. We used the Cochrane sensitivity-maximising RCT filter for MEDLINE, and for Embase, terms recommended in the Cochrane Handbook were applied (Lefebvre 2011). Adaptations of this filter were applied to CINAHL and PsycINFO. We translated the MEDLINE search strategy for use in the other databases using the appropriate controlled vocabulary as applicable. We imposed no language or other limitations and gave consideration to variations in terms used and spellings of terms in different countries so that studies would not be missed by the search strategy because of such variations. See Appendix 1 for details of the search strategies used.
Ongoing trials were identified from searching the following trial registries in May 2016:
- UK Clinical Trials Gateway (https://www.ukctg.nihr.ac.uk/)
- ClinicalTrials.gov (https://clinicaltrials.gov)
- ICTRP WHO International Clinical Trials Registry Platform (http://apps.who.int/trialsearch/)

Search results reporting was conducted in accordance with PRISMA (Moher 2009). A flow diagram is included, which provides information about the number of studies identified, included and excluded, and reasons for exclusions (Figure 1).

Figure 1. PRISMA flow diagram



Searching other resources

Reference lists of all eligible trials, systematic reviews and meta-analyses were searched for additional studies. Attempts were made to contact all study authors to obtain relevant information not available in the published manuscript.

Data collection and analysis

Selection of studies

Titles and abstracts of studies identified by the search strategy were screened by two independent review authors (LA, RST) and obviously irrelevant studies were discarded. The full-text reports of all potentially relevant abstracts were obtained (LA) and assessed independently for eligibility (LA, RST). Any disagreement was resolved by discussion. Excluded studies and reasons for exclusion are detailed in the Characteristics of excluded studiestable.

Data extraction and management

One review author (LA) extracted study characteristics of included RCTs using a standardised data collection form which had been piloted on two RCTs included in the review. Data on patient characteristics (e.g. age, sex, CHD diagnosis) details of the intervention (including duration, frequency and delivery), description of usual care and length of follow-up were extracted. A second author (HKR) checked all extracted data for accuracy. Two independent review authors (LA, HKR) extracted outcome data onto a standardised collection form. If data were presented numerically (in tables or text) and graphically (in figures), the numeric data were used because of possible measurement error when estimating from graphs. Any discrepancies were resolved by arbitration. One review author (LA) transferred extracted data into Review Manager 5.3 (RevMan 2014), and a second author (RST) checked data for accuracy against the systematic reviews.

If there were multiple reports of the same study, we assessed the duplicate publications for additional data. We extracted outcome results at all follow-up points post-randomisation. We contacted study authors where necessary to provide additional information.

Assessment of risk of bias in included studies

One review author (LA) assessed the risk of bias in included studies using Cochrane's recommended tool, which is a domain-based critical evaluation of the following core risk of bias items: the quality of random sequence generation and allocation concealment, description of withdrawals, blinding of outcome assessment, and presence of selective reporting (Higgins 2011). We also assessed three further quality criteria: whether the study groups were balanced at baseline, if the study groups received comparable care (apart from the educational component of the intervention), and whether an intention-to-treat analysis was undertaken. The criteria used for assessing these last three risk of bias domains are as follows.

Groups balanced at baseline

- *Low risk of bias*: the characteristics of the participants in the intervention and control groups at baseline is reported to be comparable or can be judged to be comparable in terms of likely main prognostic factors.
- *Uncertain risk of bias*: it is not reported whether the participants' characteristics in the two groups are balanced at baseline and there is inadequate information reported to assess this.
- *High risk of bias*: there is evidence of substantive imbalance in the baseline characteristics of the intervention and control groups with regard to likely major prognostic factors.

Intention-to-treat analysis

- *Low risk of bias*: the trial reports that the analyses were conducted according to an intention-to-treat analysis, and includes all the principles of such an analysis, e.g. keeping participants in the intervention groups to which they were randomised, regardless of the intervention they actually received; and measures outcome data on all or the majority of participants (i.e. > 80% of those randomised) or includes imputation of all missing data in the analysis, using appropriate methodology, e.g. multiple imputation.
- *Uncertain risk of bias*: it is unclear if the trial has performed an intention-to-treat analysis.
- *High risk of bias*: the trial does not include an intention-to-treat analysis, or there is a substantive loss of outcome data (e.g. > 20%) and analyses are performed according to imputation methods known to create bias such as last observation carried forward.

Groups received comparable treatment (except exercise)

- *Low risk of bias*: all co-interventions were delivered equally across intervention and control groups.
- *Uncertain risk of bias*: there was insufficient information to access whether co-interventions were equally delivered across groups.
- *High risk of bias:* the co-interventions were not delivered equally across intervention and control groups.

All risk of bias assessments were checked by a second review author (HKR) and any discrepancies were resolved by arbitration. Details of the assessments of risk of bias for each included trial are shown in the Characteristics of included studies table.

Measures of treatment effect

For dichotomous variables, risk ratios (RR) and 95% confidence intervals (CI) were derived for each outcome. If any continuous variables had been reported, mean differences and 95% CI would have been calculated for each outcome.

Unit of analysis issues

In accordance with Section 9.3.1 of the *Cochrane Handbook for Systematic Reviews of Intervention* (Higgins 2011), we ensured that the analysis was appropriate to the level at which randomisation occurred. All studies included in this review were simple parallel group RCTs, and so there were no issues relating to unit of analysis.

Dealing with missing data

We contacted investigators or study sponsors to verify key study characteristics and obtain missing numerical outcome data where possible (for example when a study is identified as an abstract only). Had this not been possible, and the missing data were thought to introduce serious bias, we planned to explore the impact of including such studies on the overall assessment of results by a sensitivity analysis.

Assessment of heterogeneity

We explored heterogeneity amongst included studies qualitatively (by comparing the characteristics of included studies) and quantitatively (using the Chi² test of heterogeneity and I^2 statistic). We used a threshold of I^2 greater than 50% for both dichotomous and continuous outcomes to determine the statistical model to be used for meta-analysis.

Assessment of reporting biases

The funnel plot and the Egger test were used to examine small study bias (Egger 1997).

Data synthesis

We processed data in accordance with *Cochrane Handbook for Systematic Reviews of Interventions* guidance (Deeks 2011). Where appropriate and possible, results from included studies were combined for each outcome to give an overall estimate of treatment effect. Given the degree of clinical heterogeneity seen in participant selection, interventions and comparators across studies, we decided it was appropriate to pool studies using random-effects modelling.

With the exception of total mortality, the review did not identify sufficient data to allow stratified meta-analysis at different common follow-up timings (e.g. 6 or 12 months post-randomisation). Instead, we pooled studies at their longest follow-up unless otherwise stated.

Summary of findings table

Two independent review authors (LA, RST) used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to interpret result findings and used GRADEpro GDT 2014 to import data from Review Manager to create a 'Summary of findings table'. We created a 'Summary of findings' table using the following outcomes: total mortality, fatal and/or non-fatal MI, total revascularisations, other fatal and/or non-fatal cardiovascular events, hospitalisations, withdrawals and HRQoL. We used the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of a body of evidence as it relates to the studies that contribute data to the meta-analyses for the prespecified outcomes. We used methods and recommendations described in Section 8.5 and Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* using GRADEpro GDT 2014 software (Higgins 2011). We justified all decisions to downgrade the quality of studies using footnotes, and made comments to aid readers' understanding of the review where necessary.

Subgroup analysis and investigation of heterogeneity

As stated in the protocol, we planned to undertake subgroup analysis and stratified meta-analysis, sensitivity analysis and meta-regression to examine potential treatment effect modifiers. We intended to test the following a priori hypotheses that there may be differences in the effect of education on total mortality and withdrawal across particular subgroups:

- CHD case mix (MI-only trials versus other trials).
- Dose and nature of structured patient education. Assessed on the basis of the number and nature of education sessions e.g. extent of training of who delivers the education, a healthcare professional, or specific educational training, whether feedback or re-inforcement were given (i.e. literature, audiovisual follow-up material).
- Method of structured educational delivery (one-to-one versus group versus combination).
- Theoretical versus no theoretical basis to educational intervention.
- Involvement of significant others (e.g. spouse, family member) in the education.
- Timing of the education following the index event.
- Length of the educational intervention.
- Follow-up period ($\leq$ 12 months versus > 12 months).

For this update we also tested the following predictors of total mortality and withdrawal using univariate meta-regression:

- mean age of participants;
- percentage of male participants;
- type of cardiac rehabilitation (education only versus education plus e.g. exercise or psychological intervention);
- study location (continent); and
- setting (centre versus home).

Due to poor reporting, we were unable to examine the association of dose of education or timing following the index event, with the risk of total mortality or withdrawal.

Sensitivity analysis

We undertook a sensitivity analysis to examine the effect of risk of bias (low risk in $\geq$ five items versus < five items) and year of publication (before 2000 versus 2000 or later) of included studies on total mortality and withdrawal.

We decided it was appropriate to pool studies using random-effects modelling, due to the clinical heterogeneity seen in participant selection, interventions and comparators across studies. However, we undertook a sensitivity analysis to examine the effect on the pooled data of conducting a fixed-effect or a random-effects model. The results of the random-effects model are reported as default in the text, while the results from both models for all outcomes are reported in Table 1.

RESULTS

Description of studies

Results of the search

We identified 3918 records through our electronic database search. After de-duplication, 2749 titles and abstracts were screened for inclusion, of which 2639 were excluded. We identified two additional records from searching the citations of publications identified as meeting our inclusion criteria, and a further 10 studies listed on trial registries. We retrieved and assessed 122 full text reports for eligibility and subsequently excluded 84 publications. Sixteen studies were ongoing and five were determined as awaiting

classification because the full text was not available and authors did not respond to repeated requests for study information. In total, we included an additional nine randomised controlled trials (RCTs) (17 publications) to the 13 RCTs (24 publications) from the 2011 review, totaling 22 RCTs (41 publications). Details of the exclusion process and reasons for exclusion are summarised in a PRISMA flow diagram (Figure 1) and in the Characteristics of excluded studies table.

Included studies

The previous version of this review (Brown 2011) included 13 RCTs (24 publications) (Clark 1997; Clark 2000; Clark 2009; Cupples 1994; Esposito 2008; Hanssen 2007; Lie 2009; Lisspers 1999; P.RE.COR Group 1991; Peikes 2009; Pogosova 2008; Southard 2003; Tingström 2005). We included an additional nine RCTs for this update (16 publications, 8215 participants) (Chow 2015; Cohen 2014; Dracup 2009; Furuya 2015; Jorstad 2013; Melamed 2014; Mooney 2014; Moreno-Palanco 2011; Park 2013). We included a total of 22 studies reporting data for a total of 76,864 participants in this update.

Details of included studies are listed in the Characteristics of included studies table. Seventeen studies compared education-only interventions with a comparator and five studies reported on an education plus counselling or behaviour change intervention (Dracup 2009; Hanssen 2007; Lie 2009; Lisspers 1999; Peikes 2009). No studies included interventions which comprised exercise as a co-intervention.

Eleven studies were undertaken in Europe (Cohen 2014; Cupples 1994; Hanssen 2007; Jorstad 2013; Lie 2009; Lisspers 1999; Melamed 2014; Mooney 2014; Moreno-Palanco 2011; P.RE.COR Group 1991; Tingström 2005); six were performed in the USA (Clark 1997; Clark 2000; Clark 2009; Esposito 2008; Peikes 2009; Southard 2003); and one each in Russia (Pogosova 2008), Australia (Chow 2015), South America (Furuya 2015) and Asia (Park 2013) and one was undertaken in sites in USA, Australia and New Zealand (Dracup 2009). Fourteen studies were multicentre RCTs (Clark 1997; Clark 2000; Clark 2009; Cohen 2014; Cupples 1994; Dracup 2009; Esposito 2008; Jorstad 2013; Melamed 2014; Mooney 2014; P.RE.COR Group 1991; Peikes 2009; Southard 2003; Tingström 2005); and eight were single centre RCTs (Chow 2015; Furuya 2015; Hanssen 2007; Lie 2009; Lisspers 1999; Moreno-Palanco 2011; Park 2013; Pogosova 2008). Sixteen studies reported sources of funding; six did not report funding sources (Clark 1997; Esposito 2008; Lie 2009; Melamed 2014; Moreno-Palanco 2011; Pogosova 2008). One study was funded by an industrial sponsor (Jorstad 2013), four by health insurance companies (Chow 2015; Cohen 2014; Lisspers 1999; Peikes 2009) and 11 by government or public sources (Clark 2000; Clark 2009; Cupples 1994; Dracup 2009; Furuya 2015; Hanssen 2007; Mooney 2014; P.RE.COR Group 1991; Park 2013; Southard 2003; Tingström 2005).

Most trials were relatively small in sample size (median 454 participants, range: 63 to 46,606). Two large trials (Esposito 2008; Peikes 2009) contributed 85% (65,008 participants) of all included participants.

The median duration of trial intervention was six months (range 1 to 36 months) with median follow-up of 12 months (range 6 to 60 months).

The case mix of participants recruited to the included trials varied considerably; six studies recruited mixed populations of people with CHD (Chow 2015; Clark 1997; Clark 2000; Clark 2009; Melamed 2014; Pogosova 2008); four studies recruited participants with myocardial infarction (MI) or angina (Cohen 2014; Jorstad 2013; Mooney 2014; Park 2013); and the remaining studies recruited participants post-revascularisation (Furuya 2015; Lie 2009; Lisspers 1999); with coronary heart disease (CHD) or heart failure (Esposito 2008; Peikes 2009; Southard 2003); MI (Hanssen 2007; P.RE.COR Group 1991); acute coronary syndromes (ACS) (Dracup 2009; Moreno-Palanco 2011); angina (Cupples 1994); or MI or post-revascularisation (Tingström 2005).

The mean age of trial participants ranged from 51.0 to 72.8 years. Although all but two trials included women (20 studies, 91%), only 25% of participants recruited were women.

The two largest studies (65,008 participants) (Esposito 2008; Peikes 2009) included some participants who were outside the scope of this review (i.e. trialists considered people with congestive cardiac failure and diabetes). However, participants with CHD contributed 69% and 61% respectively, to these studies. Both studies reported hospitalisation, health-related quality of life (HRQoL) and cost data. Only hospitalisation data from Esposito 2008 contributed to the meta-analysis, and these data were reported separately for participants with CHD (Esposito 2008). Southard 2003 included participants with cardiac failure as well as those with CHD.

Four studies involved group sessions (Clark 1997; Clark 2000; Pogosova 2008; Tingström 2005); 12 involved individual education sessions (Chow 2015; Cohen 2014; Cupples 1994; Dracup 2009; Esposito 2008; Hanssen 2007; Lie 2009; Melamed 2014; Moreno-Palanco 2011; Mooney 2014; Park 2013; Peikes 2009); three used both group and individual sessions (Lisspers 1999; P.RE.COR Group 1991; Southard 2003); one study compared group and individual approaches (Clark 2009); and one study did not report on the mode of teaching (Jorstad 2013). Eighteen studies involved face-to-face sessions (Cohen 2014; Dracup 2009; Clark 1997; Clark 2000; Clark 2009; Cupples 1994; Esposito 2008; Furuya 2015; Jorstad 2013; Lie 2009; Lisspers 1999; Melamed 2014; Moreno-Palanco 2011; Mooney 2014; P.RE.COR Group 1991; Park 2013; Pogosova 2008; Tingström 2005); three were reliant on telephone contact (Esposito 2008; Hanssen 2007; Peikes 2009); three used face-to-face sessions as well as telephone follow-up (Furuya 2015; Mooney 2014; Park 2013); one involved interactive use of the Internet (Southard 2003); and one used text messages via a mobile phone (Chow

2015). The educational intervention was delivered by a wide variety of personnel, with nine interventions delivered by nurses (Cohen 2014; Dracup 2009; Esposito 2008; Furuya 2015; Hanssen 2007; Jorstad 2013; Lie 2009; Mooney 2014; Moreno-Palanco 2011); four by trained educators (Clark 1997; Clark 2000; Clark 2009; Tingström 2005); three by physicians (Melamed 2014; P.RE.COR Group 1991; Pogosova 2008), and one each by a care co0ordinator (Peikes 2009), case manager (Southard 2003), and a researcher (Furuya 2015). The person delivering the intervention was not described in one study (Park 2013). The intensity of the education programme varied substantially from just one 40 minute face-to-face session plus a 15 minute follow-up call (Dracup 2009) to a four-week residential stay reinforced with 11 months of nurse-led follow-up sessions (Lisspers 1999). Description of the educational content of the programmes was mostly brief and lacked detail. Table 2 summarises educational interventions.

Excluded studies

We excluded 84 full text publications because they did not meet the inclusion criteria for this review (see Characteristics of excluded studies). Seven studies were not RCTs, 13 studies had follow-up periods of less than six months, three studies included populations who were irrelevant for this Review, 36 studies investigated interventions that were not relevant to this Review, six included inappropriate comparators and 19 studies did not report outcomes that were relevant to this Review.

Ongoing studies

The details of 16 ongoing studies that appear to meet the inclusion criteria for this Review are presented in Characteristics of ongoing studies (ACTRN12613000395730; ACTRN12613000793718; ACTRN12616000426482; Brewer 2015; Dwinger 2013; IRCT201307162621N13; ISRCTN15839687; Kärner 2012; Lai 2016; Lynggaard 2014; NCT01028066; NCT01275716; NCT01925079; NCT02185391; NTR2388; Shah 2011).

Studies awaiting classification

The details of five studies that are awaiting classification are presented in Characteristics of studies awaiting classification.. One study was published in the IIOAB Journal, but we were not able to access any of this journal's web pages (Gao 2011). We were unable to find the full text or trace the authors of the remaining four studies (Licina 2010; Soliman 2013; Vona 2009; Xiaolin 2012).

Risk of bias in included studies

Several studies did not report sufficient methodological detail to enable assessment of potential risk of bias. Details of random sequence generation, concealment of random allocation and blinding were the most frequent poorly reported parameters. Risk of bias results are summarised in Figure 2 and Figure 3.

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

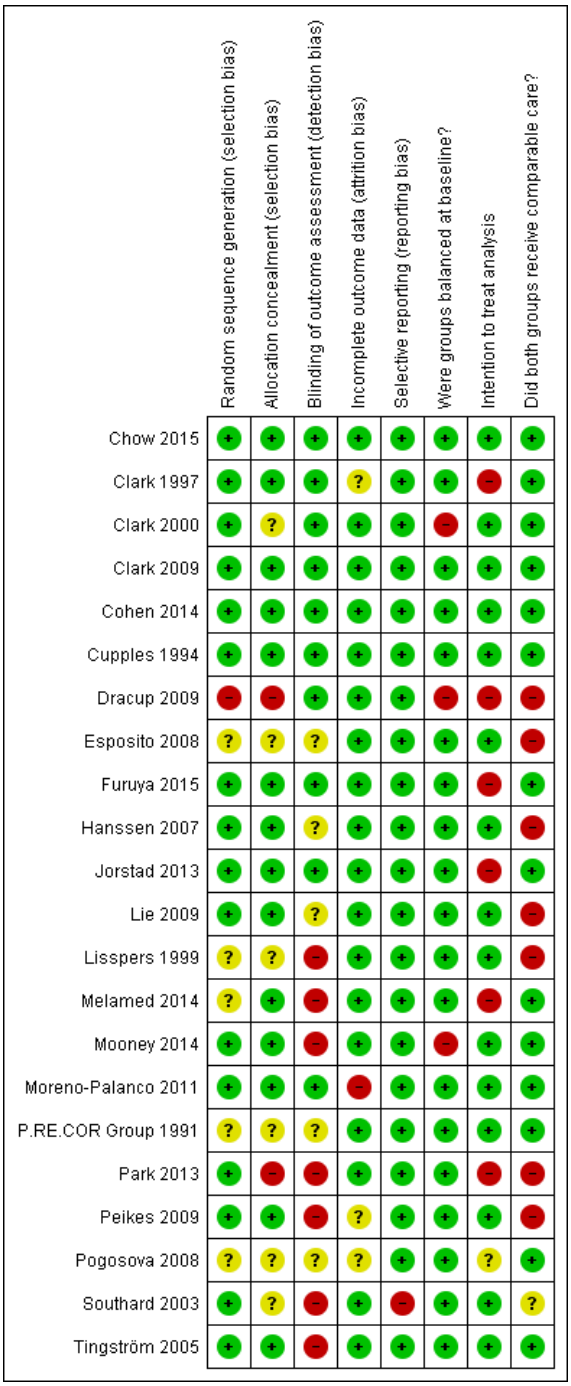
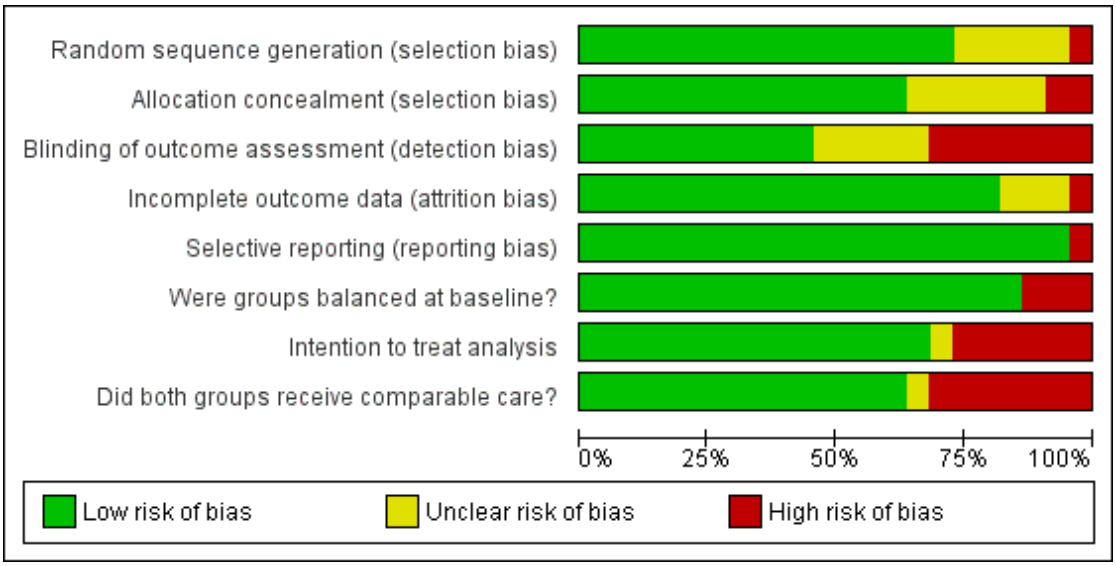


Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies



Allocation

Sixteen studies were judged to provide evidence of adequate random sequence generation (Chow 2015; Cohen 2014; Clark 1997; Clark 2000; Clark 2009; Cupples 1994; Furuya 2015; Hanssen 2007;Jorstad 2013; Lie 2009; Mooney 2014; Moreno-Palanco 2011; Park 2013; Peikes 2009; Southard 2003; Tingström 2005). Fourteen studies reported adequate concealment methods (Chow 2015; Clark 1997; Clark 2009; Cohen 2014; Cupples 1994; Furuya 2015; Hanssen 2007; Jorstad 2013; Lie 2009; Melamed 2014; Mooney 2014; Moreno-Palanco 2011; Peikes 2009; Tingström 2005).

Blinding

Due to the nature of the educational intervention, it was not possible to blind education providers or trial participants. We investigated evidence to ascertain if those collecting, assessing or analysing outcome data were blinded to group allocation. Blinding of this nature was confirmed in 10 studies (Chow 2015; Cohen 2014; Clark 1997; Clark 2000; Clark 2009; Cupples 1994; Dracup 2009; Furuya 2015; Jorstad 2013; Moreno-Palanco 2011).

Incomplete outcome data

Sixteen studies clearly stated withdrawal or numbers lost to follow-up (Table 3). Overall, 11.3% of participants in intervention groups and 11.5% of control group participants were lost to follow-up. Most authors failed to assess participants who were lost to follow-up for systematic differences when compared to those who completed the study.

Selective reporting

We compared the reported outcomes in the results sections to the outcomes described in the methods of published papers. No attempt was made to identify original study protocols and compare these to reported outcomes. Only one study demonstrated selective reporting by not reporting the results of a HRQoL measure (Southard 2003).

Other potential sources of bias

Baseline balance

Eighteen studies had a good balance of subject baseline characteristics between intervention and control groups. Four studies demonstrated a statistically significant imbalance between groups at baseline (Clark 2000; Dracup 2009; Mooney 2014; Peikes 2009). There were differences in baseline disease symptoms and weight in Clark 2000. Peikes 2009 highlighted 11 differences in 255 baseline characteristics compared between groups, which they qualified as "less than the expected number of statistical significant differences than would be observed by chance (Peikes 2009). In Dracup 2009, there were differences in baseline body mass index, gender (with more females in the experimental group than control, P = 0.02), and insurance for ambulance use. In Mooney 2014, there were some significant differences between characteristics and prognostic factors of the two groups at baseline including age.

Intention-to-treat analysis

Fifteen studies analysed results on an intention-to-treat basis (Chow 2015; Cohen 2014; Clark 2000; Clark 2009; Cupples 1994; Esposito 2008; Hanssen 2007; Lie 2009; Lisspers 1999; Mooney 2014; Moreno-Palanco 2011; P.RE.COR Group 1991; Peikes 2009; Southard 2003; Tingström 2005). In most cases, this involved analysing those participants remaining at follow-up according to initial randomisation. Clark 1997 did not present intention-to-treat data, but presented data for participants who had attended at least one of the four intervention sessions.

Comparative care

We specifically sought to investigate the impact of education. However, in addition to education (the primary intervention), participants appeared to receive other co-interventions such as exercise or psychological therapy in a number of studies. It was unclear how much of these co-interventions were received by control group participants, posing potential for performance bias (Dracup 2009; Esposito 2008; Hanssen 2007; Lisspers 1999; Park 2013; Peikes 2009; Southard 2003).

Effects of interventions

See: **Summary of findings for the main comparison** Patient education for the management of coronary heart disease

Primary outcomes

Total mortality

Thirteen studies (10,075 participants) reported total mortality. Two studies reported deaths at six months (Chow 2015; Furuya 2015); five at 12 months (Clark 2000; Cohen 2014; Dracup 2009; Jorstad 2013; Mooney 2014); two at 18 months (Clark 2009; Hanssen 2007); four at 24 months (Clark 2000; Cupples 1994; Lisspers 1999; P.RE.COR Group 1991); one at 36 months (Moreno-Palanco 2011) and two at 60 months (Cupples 1994; Lisspers 1999). Only one study demonstrated a significant difference in total mortality between education and control, where the cumulative survival rate at three years was 97.4% in the intervention group and 85.5% in the control group (P = 0.003) (Moreno-Palanco 2011). At the longest reported follow-up, there was evidence of no difference in effect of education-based interventions on total mortality (random effects RR 0.80, 95% CI 0.60 to 1.05; participants = 10,075; studies = 13; Analysis 1.1).
Quality of the evidence for this outcome was judged to be moderate (Summary of findings for the main comparison).
When data were stratified by length of follow-up, there was similar uncertainty of the effect of education-based interventions on total mortality for those studies with a mean length of follow-up of more than 12 months (random effects RR 0.78, 95% CI 0.60 to 1.02; participants = 6012; studies = 7). There was evidence of no reduction in total mortality in studies with a mean length of follow-up of 12 or fewer months (random effects RR 0.78, 95% CI 0.35 to 1.78; participants = 4063; studies = 6).

Cardiovascular mortality

Individual causes of mortality were poorly or not reported across studies. We were therefore unable to report separate data for cardiovascular mortality.

Non-cardiovascular mortality

Individual causes of mortality were not reported across studies. We were therefore unable to report separate data for non-cardiovascular mortality.

Fatal and/or non-fatal myocardial infarction (MI)

Two studies reported fatal and/or non-fatal MI (Lisspers 1999; P.RE.COR Group 1991). There was evidence of no reduction in morbidity with education-based interventions for fatal and/or non-fatal MI (random effects RR 0.63, 95% CI 0.26 to 1.48; participants = 209; studies = 2; Analysis 1.2).
Quality of the evidence for this outcome was judged to be very low (Summary of findings for the main comparison).

Other fatal and/or non-fatal cardiovascular events

Two studies reported other fatal or non-fatal cardiovascular events (Moreno-Palanco 2011; Park 2013, 310 participants). There was some evidence of a reduction in other fatal or non-fatal cardiovascular events with education-based interventions (random effects RR 0.36, 95% CI 0.23 to 0.56; participants = 310; studies = 2; Analysis 1.3).

Quality of the evidence for this outcome was judged to be low (Summary of findings for the main comparison).

Southard 2003 reported a difference in "major cardiovascular-related events"; fewer events occurred in the intervention group (P = 0.053). These were defined as events needing hospitalisation either as an inpatient or from the emergency department. As other cardiovascular events may have occurred that did not meet this definition, it was not appropriate to include these data in the pooled analysis.

Secondary outcomes

Total revascularisations (coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI))

Three studies (456 participants), reported subsequent revascularisation (CABG or PCI) (Lisspers 1999; Moreno-Palanco 2011; P.RE.COR Group 1991). There was evidence of no reduction in morbidity with education for total revascularisations (random effects RR 0.58, 95% CI 0.19 to 1.71; participants = 456; studies = 3; Analysis 1.4).

Quality of the evidence for this outcome was judged to be very low (Summary of findings for the main comparison).

Hospitalisations

Seven studies reported cardiac-related hospitalisations (Clark 2000; Esposito 2008; Hanssen 2007; Lisspers 1999; Mooney 2014; Peikes 2009; Southard 2003).

We pooled the results of the five studies (14,849 participants) that reported numbers of participants who were hospitalised for cardiac-related events (Esposito 2008; Hanssen 2007; Lisspers 1999; Mooney 2014; Southard 2003). There was evidence of no reduction in hospitalisation with education-based interventions (random effects RR 0.93, 95% CI 0.71 to 1.21; participants = 14,849; studies = 5; Analysis 1.5.

Quality of the evidence for this outcome was judged to be very low (Summary of findings for the main comparison).

Due to the method of reporting hospitalisations in four studies, it was not possible to include these in the pooled analysis (Clark 2000; Dracup 2009; Jorstad 2013; Peikes 2009).

Using intention-to-treat analysis Clark 2000 found no statistically significant difference in the total number of hospitalisations between intervention and control. Analysis of the "heart-related admissions" in those participants who attended at least one intervention session revealed statistically significant reductions in the intervention group: participants in the intervention group had 41% fewer "heart-related admissions" (P = 0.05) and 61% fewer "heart-related" inpatient days (P = 0.02) than in the control group (Clark 2000).

Dracup 2009 reported the number of participants who presented to the emergency department with symptoms of ACS (565 participants (16.0%) and a total of 842 admissions). Of the 565 participants, 305 (54%) were in the intervention group and 260 (46%) were in the control group. Of the 842 emergency department admissions, 408 (48%) were in the control group and 434 (52%) were in the intervention group.

Jorstad 2013 reported the cumulative number of re-admissions in 12 months. In total, there were 86 rehospitalisations in the intervention group and 132 in the control group (P = 0.023) (Jorstad 2013). This difference was driven by a 67% reduction in re-admissions for non-ACS chest pain (12 admissions versus 36 admissions, P < 0.001); re-admissions for ACS and elective interventions were comparable in both groups.

Peikes 2009 reported the rate of hospitalisations across 15 different USA study sites. Overall, there was no clear evidence of effect of intervention, with only two of 15 sites showing a significant difference in hospital admissions. One reported an increase in admissions in the intervention group and the other reported an increase in the control group. No between-group statistical difference was found in average annualised admission rates 0.91 (intervention) versus 0.95 (control) (P = 0.145).

Withdrawals

Studies varied in their reporting of participants who withdrew or dropped out of the study, the analysis or both. Most studies failed to report the number of participants who withdrew because they were unable to complete the intervention. Therefore, we reported withdrawals at follow-up (Table 3). There was evidence of no difference in the number of withdrawals from the education-based intervention or control groups (random effects RR 1.04, 95% CI 0.88 to 1.22; participants = 10,972; studies = 17; Analysis 1.6).

Results remained equivocal when data were stratified by length of follow-up (mean follow-up $\leq$ 12 months: random effects RR 1.18, 95% CI 0.93 to 1.49; participants = 4960; studies = 10; mean follow-up > 12 months: random effects RR 0.98, 95% CI 0.80 to 1.20; participants = 6012; studies = 7).

Quality of the evidence for this outcome was judged to be low (Summary of findings for the main comparison).

Clark 1997 reported a combined withdrawal of 181 participants from both groups. A differential breakdown was not given, but there was "no appreciable differences in withdrawal rates between the intervention and control group" demonstrated (Clark 1997).

Numbers lost to follow-up were unclear in four studies (Esposito 2008; Lisspers 1999; Peikes 2009; Pogosova 2008).

Health-related quality of life (HRQoL)

Fifteen studies reported HRQoL (Cohen 2014; Clark 1997; Clark 2000; Clark 2009; Cupples 1994; Esposito 2008; Furuya 2015; Hanssen 2007; Lie 2009; Lisspers 1999; Melamed 2014; Park 2013; Pogosova 2008; Southard 2003; Tingström 2005). These studies used several generic HRQoL instruments, i.e. SF-12

(Cohen 2014; Furuya 2015), SF-36 (Furuya 2015; Hanssen 2007; Lie 2009; Pogosova 2008; Tingström 2005), Nottingham Health Profile (Cupples 1994), Sickness Impact Profile (Clark 1997; Clark 2000), a five-point patient assessment scale of quality of life (Cupples 1994) and two disease-specific HRQoL instruments i.e. Seattle Angina Questionnaire (Lie 2009; Park 2013), AP-QLQ (Angina Pectoris-Quality of Life Questionnaire) (Lisspers 1999) and the MacNew Heart Disease Quality of Life Questionnaire (Melamed 2014). The wide variation in HRQoL outcomes and methods of reporting meant we were unable to meta-analyse results. Instead, we undertook a detailed tabulation of the overall and domain HRQoL scores from each of the trials with a particular focus on intervention-control differences at follow-up. To provide some level of overall synthesis, for each study we assessed whether total and domain HRQoL between-group differences were statistically different and, if so, the direction of effect (Table 4; Table 5; Table 6; Table 7; Table 8; Table 9; Table 10; Table 11; Table 12; Table 13; Table 14; Table 15; Table 16; Table 17).

Whilst overall we found no consistent difference in HRQoL total or domain score at follow-up between intervention and comparator, a number of studies reported statistically significant differences in HRQoL domains in favour of intervention (Clark 1997; Clark 2000; Cupples 1994; Park 2013). Pogosova 2008 demonstrated an improvement in all SF-36 domain scores and Lie 2009 an improvement in the overall mental score in the intervention groups. No studies reported HRQoL scores that favoured the comparator group.

Although Southard 2003 reported Dartmouth COOP Quality of Life scores at trial entry, there were no reports of this outcome at follow-up. Esposito 2008 reported on a HRQoL questionnaire undertaken in a randomly selected subgroup of patients from the overall trial. No significant differences were found between the intervention and control groups in a number of measures of mental and physical status, including: "Primary condition interfered a lot or somewhat with enjoyment of life in the last 4 weeks" (between-group difference -3.6% (in favour of intervention) P = 0.379); "Beneficiary felt primary condition placed a burden on family in the past 4 weeks" (between-group difference 0.5% P = 0.897); "Beneficiary felt depressed about living with primary condition in the past 4 weeks" (between-group difference 1.2% (in favour of control) P = 0.766).

Adverse events

Few studies reported on adverse events other than mortality and cardiovascular-related morbidity and hospitalisations. Cohen 2014 reported numbers of participants in the intervention and usual care groups with arrhythmia (1.6% and 2.8% respectively); coronary angiography (7.3% and 8.9%); scheduled angioplasty (4.9% and 3.2%); ACS, stent thrombosis, or chest pain (13.5% and 12.6%); and dyspnoea, lung oedema, or congestive heart failure (3.7% and 2.4%). Esposito 2008 reported that there were no significant differences between the groups in the number of preventable events such as hospitalisations for pneumonia or exacerbations of heart failure, or lower-extremity amputations in patients with diabetes.

No study reported any intervention-related adverse events such as prohibitive time or travel demands which would prevent participation in the intervention.

Healthcare costs and cost-effectiveness

Five studies reported healthcare utilisation and costs (Clark 2000; Cupples 1994; Esposito 2008; Peikes 2009; Southard 2003). Given that cost results were presented in different currencies and incurred in different years, it was difficult to directly compare studies. Furthermore, although studies assessed healthcare costs, there was variation in the particular aspects of healthcare costs that were quantified. Components of costs considered included inpatient admissions, primary care visits, emergency attendances, use of drugs, investigations and subsequent procedures performed. To compare studies and gain an overall impression of the differences in healthcare between intervention and control, we undertook a detailed tabulation of the overall and component healthcare costs for each of the included studies (Table 18).

Reflecting the different education modalities and intensities of the interventions, the reported cost of provision per patient varied from GBP 49 (Cupples 1994) to USD 453 (Southard 2003). The largest trials, investigating the efficiency of the Medicare system in the USA (Esposito 2008; Peikes 2009), did not investigate the cost of providing the intervention but instead reported the charge associated with providing this service negotiated by the supplier (care co-ordination fee). Peikes reported a mean of USD 196 per month (Peikes 2009), while Esposito reported a mean of USD 162 per month (Esposito 2008).

Two studies reported an overall average net saving, after subtracting costs of intervention provision, of USD 965 per patient at six-months follow-up (Southard 2003) and USD 1420 per patient at 24-months follow up (Clark 2000). Peikes 2009 reported an increase in average net costs of USD 52 per patients; six of the 15 programmes investigated had higher costs for the intervention group. Two trials found no difference in between-group net costs (Cupples 1994; Esposito 2008).

Meta-regression and stratified meta-analysis

Predictors of total mortality and all-cause withdrawal were examined across the longest follow-up of each individual study using univariate meta-regression (Table 19; Table 20). We found no evidence that total mortality risk was associated with case mix, age of participants, percentage of male participants, type of cardiac rehabilitation, method of delivery, duration of intervention, theoretical basis of intervention, involvement of family members, study location, setting, or length of follow-up (Table 19). Similarly, we

found no associations between predictors of withdrawal, with the exception of evidence of an increased risk of withdrawal in studies with shorter follow-up periods (Table 20). Due to poor reporting we were unable to examine the association of dose of education or timing following the index event with the risk of total mortality or withdrawal.

Sensitivity analysis

Sensitivity analysis found no evidence that total mortality risk was associated with year of publication (before 2000 versus 2000 or later), or risk of bias (Table 21). Similarly, we found no associations between risk of withdrawal and year of publication, but did see evidence of an increased risk of withdrawal in studies with higher risk of bias (low risk in ≥ five items versus < five items) (Table 22).

Data for all outcomes were pooled using both random-effects and fixed-effect modelling (Table 1). With the exception of hospitalisations and withdrawals at the longest follow-up, the direction of effect of all outcomes was the same, regardless of the model used. Similarly, with the exception of total mortality, the choice of model used did not change whether or not the confidence intervals included the null hypothesis.

Small study bias

With the exception of total mortality and withdrawals, there were too few studies and outcome data to assess small study bias by means of funnel plots or Egger's test. There was no evidence of funnel plot asymmetry or statistically significant Egger's test for total mortality (Figure 4 P = 0.83) or withdrawals (Figure 5; P = 0.10).

Figure 4. Funnel plot of comparison: 4 Education versus no education, outcome: 4.1 Total mortality at the end of the follow up period.

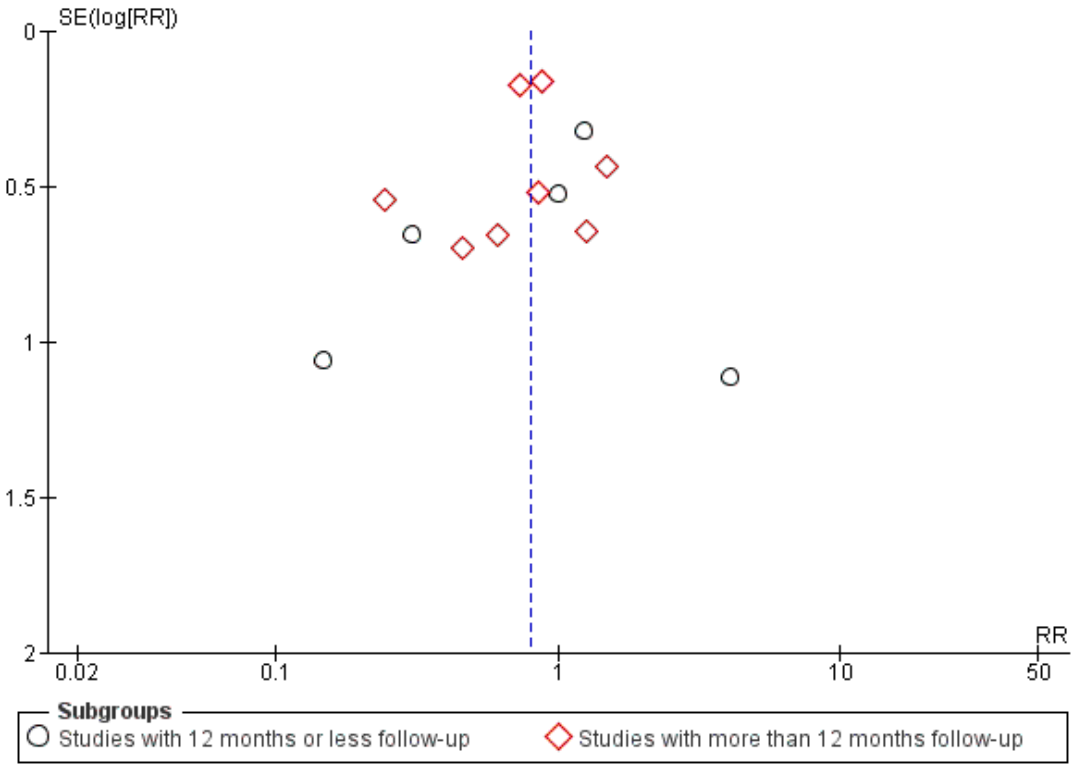
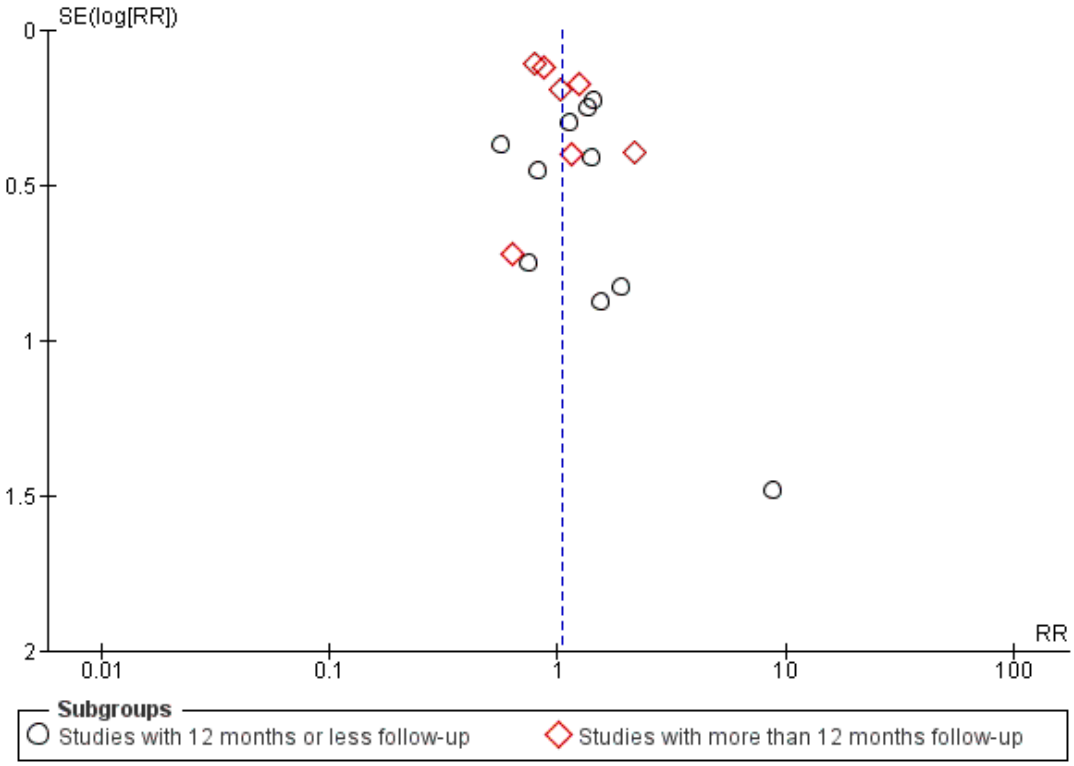


Figure 5. Funnel plot of comparison: 1 Education versus no education, outcome: 1.6 Withdrawals.



Quality of evidence from randomised controlled trials

The quality of the evidence for outcomes reported in the review was rated using the GRADE method (Schünemann 2011). The quality of the evidence varied widely by outcome and ranged from very low to moderate (see Summary of findings for the main comparison). The reasons for downgrading evidence of outcomes included poor reporting of blinding of outcome assessors in at least 50% of the studies which contributed data to the evidence, evidence of heterogeneity (I^2 > 50%), or imprecision around the point of effect.

DISCUSSION

Summary of main results

We included 22 randomised controlled trials (RCTs) involving 76,864 participants with coronary heart disease (CHD) where education was the primary interventional intent of cardiac rehabilitation. The 'dose' of the education intervention varied substantially across studies from just one 40 minute face-to-face session plus a 15 minute follow-up call (Dracup 2009) to a four-week residential stay re-inforced with 11 months of nurse-led follow up sessions (Lisspers 1999). Control participants typically received usual medical care without a formalised cardiac rehabilitation or secondary prevention education programme.

We found evidence of no difference in effect of education on total mortality compared with control. Pooled data for total mortality translates to a possible reduction of 18 deaths per 1000 people, to an increase in two deaths per 1000 people, compared with the assumed risk in the control group of 46 deaths per 1000 (Summary of findings for the main comparison). As individual causes of mortality were not reported across studies, we were unable to report separate data for cardiovascular mortality or non cardiovascular mortality. We found no evidence that education reduced fatal and/or non-fatal myocardial infarction (MI). We found some evidence of a reduction with education in other fatal and/or non-fatal cardiovascular events, although this was based only on two studies (310 participants). We found no evidence that education reduced revascularisations, or hospitalisation, compared to control groups receiving no education.

Univariate meta-regression analysis shows that the impact of education on total mortality appears to be largely consistent across trials irrespective of case mix (percentage of post-MI participants), type of rehabilitation (exercise-only versus comprehensive), dose of education, duration of follow-up, study location, study setting or risk of bias. As most studies had a relatively short follow-up, these results were based on very few events, and therefore, our meta-analysis lacks sufficient statistical power to make definitive conclusions about the impact of educational interventions on events in people with CHD.

Although health-related quality of life (HRQoL) was reported by almost all included studies, we were unable to pool findings due to the heterogeneity of measures. Whilst there was some evidence of higher HRQoL in some domain scores, overall there was no consistent evidence of superior HRQoL following education compared to control. Many studies used generic HRQoL measures that are known to lack sensitivity with cardiac treatment, particularly in comparison with disease-specific measures (Cohen 2014; Furuya 2015; Oldridge 2003; Taylor 1998).

The intention of including analysis of withdrawal from the intervention was to use it as a surrogate for the adverse effects of the intervention, e.g. the educational intervention was so demanding that it could not be completed by participants. However, despite withdrawals being reported by most studies, the reasons for withdrawal were not always clearly described. We found no increase in withdrawals with education compared to control.

The search for this update identified no new studies that reported healthcare costs or cost-effectiveness data. As previously reported (Brown 2011), different currencies and the years in which studies were conducted, made it difficult to directly compare healthcare costs across studies. The cost of the educational intervention varied widely (between GBP 49 and USD 453 per patient) reflecting the differing intensity and requirements for provision of the interventions investigated. There was some evidence that when compared to usual care, patient education may be cost-saving as a result of a reduction in downstream healthcare utilisation.

Overall completeness and applicability of evidence

The scope of this review was limited in its design in three specific ways:

1. Inclusion only of studies published in 1990 or later;
2. Inclusion only of studies where the educational component was the primary intention of the intervention; and
3. Inclusion only of studies that reported event data (e.g. total mortality) as opposed to intermediate outcomes (e.g. blood pressure, exercise tolerance).

These limitations in scope were crucial in addressing the specific question of what is the 'added value' of patient education in the context of contemporary cardiovascular management. The interpretation of previous systematic reviews of patient education have been confounded by including multicomponent rehabilitation interventions, of which education was only an element, and reporting on studies using surrogate outcomes such as health knowledge or blood pressure. Indeed, many of the trials identified and considered in this review process only investigated outcomes such as cardiovascular risk factor reduction, or pre-hospital delay from time of symptom onset to hospital arrival, and have not been included in this review.

In spite of the focus of this review, there was considerable heterogeneity of participants and interventions. Several studies included CHD in combination with comorbidities such as diabetes, hypertension or a degree of heart failure (Esposito 2008; Peikes 2009; Southard 2003) and interventions varied substantially in content, mode of delivery and dose. It could be argued that a benefit of this heterogeneity is that the results are more likely to be applicable to the wider population of people with CHD and clinical practice. However, we must acknowledge that different components of the educational intervention may contribute to the composite effect of the education to varying extents. Similarly, fidelity (whether the intervention was delivered as intended) and dose (the quantity of intervention implemented) are important aspects of the delivery of a complex intervention such as cardiac rehabilitation, which were not reported by any included studies.

Previous reviews of patient education, and more broadly cardiac rehabilitation, have identified the paucity of research into outcomes in women and the elderly. However, this review includes several studies with a substantive proportion of women (Clark 2000) and older people (Clark 2009) specifically addressing this disparity. Nevertheless, ethnic minorities remain under-represented, with a mean of 84% of participants described as Caucasian in studies that reported ethnicity.

Quality of the evidence

The general lack of reporting of methods in some of included RCTs made it difficult to assess methodological quality and thereby judge risk of bias. Details were often poorly reported and confirmation of methodology needed to be sought from some authors. Interestingly, reporting of methods was inferior in some of the more recent studies to many of the older studies, leading to a higher risk of selection and attrition bias than was reported in the previous version of this review (Brown 2011). The area of greatest potential risk of bias in this review was detection bias (lack of outcome assessment blinding), with less than half the studies providing sufficient details to judge if outcomes were assessed by researchers blinded or independent to the trial.

Due to this poor reporting, the quality of the evidence for outcomes was assessed as moderate at best. Other reasons for downgrading the quality of evidence included inconsistency (hospitalisations), and imprecision (total mortality, hospitalisations, subsequent MI, revascularisations and withdrawal).

The other area of potential risk of bias was the imbalance of co-interventions received by intervention and control subjects, which made it difficult to investigate the specific impact of education on outcomes. We specifically selected studies on the basis of education being the primary intervention. However, a number of studies appeared to include additional elements (e.g. behaviour modification or psychological support) in the educational intervention arm, which led to a risk of performance bias. Whilst the decision to include studies was made independently by two review authors, the decision was ultimately one of judgement based on the description of the intervention provided by the authors. During correspondence, the lead author of one included study stated: "I would not define our program as 'patient education' (at least according to the way I define this term) - more as a 'behaviour change program'...we ...very much tried to develop active program components which actually and concretely supported the behaviour change process in the short term and for the long-term maintenance" (Lisspers 1999). We would argue that a key objective of patient education is to change behaviour, i.e. through education, patients learn to understand the reasoning for improved diet, exercise regime and compliance with medication and are, therefore, more likely to modify their behaviour. This objective is consistent with adult learning theory; learning is the outcome of education and can be defined as "a relatively permanent change in behaviour as a result of experience, training or practice" (Reece 2007).

Potential biases in the review process

We believe this is the most comprehensive systematic review to date of RCT-based evidence for the impact of education-based cardiac rehabilitation for people with CHD. However, our review has some limitations. Given the inconsistent reporting of outcomes, we were unable to judge the degree of publication bias for most outcomes, although there was no evidence of funnel plot asymmetry or statistically significant Egger's test for total mortality or all-cause withdrawal. Although a specific goal of this updated review was to clarify the impact of education programmes on clinical events, many of the included trials were relatively small and had short-term follow-up periods so that the number of deaths and hospitalisations reported by most trials was small. Indeed, in many studies, we located event data in the trial descriptions of losses to follow-up and exclusions, rather than as stated primary or secondary outcomes. We also acknowledge that the median outcome follow-up of 12 months is limited when assessing for impact on total mortality and morbidity outcome measures. However, reassuringly, our results were consistent when pooling was limited to RCTs with a follow-up more than 12 months.

In this updated review, we had hoped to categorise the CHD diagnoses of trial participants according to a more detailed framework based on Braunwald's classification of CHD (Braunwald 2011) and current clinical management of CHD. However, given the lack of details of trial participants, this more detailed assessment of diagnostic groups was not possible. All participants in the included studies had documented CHD; most had experienced MI or undergone revascularisation. As with the previous version of this review, we combined these different participant groups because there were insufficient data to stratify trials by CHD type. Finally, the mean age of participants in the included trials ranged from 51.0 years to 72.8 years. Elderly participants in clinical trials are under-represented with only 14% of participants in clinical trials reported to be aged over 75 years (Dodd 2011). Yet, Myocardial Ischaemia National Audit Project registry data indicate that around 40% of people with ACS are in that age group (Zaman 2014). Clinical trial participants are therefore unlikely to be truly representative of, and are likely to have relatively fewer comorbidities than, the more frail, older population seen in clinical practice (Alexander 2007; Zaman 2014).

Agreements and disagreements with other studies or reviews

The findings of this updated review are largely in accord with the previous version (Brown 2011). In this update, we identified nine new RCTs looking at the effect of education on people with CHD. Disappointingly, few studies reported additional total mortality or event data, and consequently, the results of this update remain largely unchanged. While the previous version showed no evidence for the effect of education when delivered as part of cardiac rehabilitation on total mortality in people with CHD, this review found evidence of a reduced risk for this outcome (random effects RR 0.80, 95% CI 0.60 to 1.05; fixed effect RR 0.80, 95% CI 0.66 to 0.97, moderate quality evidence). Similarly, early systematic reviews by Mullen 1992 and Dusseldorp 1999, reported a statistically significant reduction in mortality and morbidity in people with CHD following an educational intervention. These earlier reviews included studies with multidimensional interventions (e.g. education plus psychological interventions), non-randomised studies, and studies conducted before 1990 prior to the era of optimal medical therapy. Given the proven survival advantage of contemporary medical treatments, and the limited opportunity for mortality gain in this patient cohort, any incremental total mortality benefit with education is likely to be small.

A more recent systematic review that investigated the impact of education on patients' knowledge and health behaviour change in patients with CHD reported that educational interventions in cardiac care increased patients' knowledge and facilitated behaviour change (Ghisi 2014). Educational interventions were found to lead to increases in physical activity, healthier dietary habits and smoking cessation, but no associations between education and cardiac symptoms, medication adherence or psychosocial well-being were found (Ghisi 2014).

AUTHORS' CONCLUSIONS

Implications for practice

Our findings provide limited evidence in support of the use of educational interventions for people with coronary heart disease (CHD). Given the uncertainty of the evidence of effect and the moderate (at best) quality of evidence for all outcomes, educational interventions for people with CHD should only be considered as part of a comprehensive programme that includes exercise and psychological support. This is in accordance with current evidence and international guidelines for secondary prevention and cardiac rehabilitation (Anderson 2016; BACPR 2012; Balady 2007; NICE 2007; NICE 2013; Richards 2017).

Implications for research

Given the heterogeneity in educational interventions seen in the included studies, this review reflects current uncertainty about the optimal approach of offering education to people with CHD. Further studies with longer durations and follow-up periods are needed to compare the content and intent of individual educational interventions and their relative impact on reducing risk factors, changing patient behaviour and preventing unnecessary hospital re-admissions and emergency department visits by people with CHD. Studies also need to assess the relative costs and benefits of different methods and approaches of delivering the educational content by comparing group versus individual delivery, face-to-face versus self help manuals, as well as exploring new technologies for delivering educational content. Studies should also include under-represented groups (e.g. people aged over 65 years, ethnic minorities or people from lower socio-economic settings) to increase the generalisability of outcomes to the wider population of people with CHD.

Research methods should not only be well designed, but also include a parallel qualitative process evaluation to assess fidelity and quality of delivery and to better understand patients' expectations and needs. Such studies should be conducted in the context of a multi-interventional approach to secondary prevention and rehabilitation and report sufficient information to enable replication of the interventional approach.

Improved reporting, including participant characteristics (e.g. diagnoses), and the content, dose and mode of delivery of educational intervention, is needed. This would enable future reviews to stratify outcomes according to the range of CHD populations or types of cardiac rehabilitation interventions to help better understand the optimal approach for delivering education to these patient groups.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Chow 2015

Methods	**Study design:** Single centre RCT **Country:** Australia **Dates patients recruited:** September 2011 to November 2013 **When randomised:** After hospital discharge **Maximum follow up:** 6 months
Participants	**Inclusion criteria:** Patients were eligible if they were aged > 18 years, had documented CHD, and were able to provide informed consent. **Exclusion criteria:** Patients were excluded if they did not have an active mobile phone or sufficient English language proficiency to read text messages. **N randomised: total:** 710**; intervention:** 352**; comparator:** 358 **Diagnosis (% of pts):** CHD**:** 100% **Age (mean ± SD): total:** 57.6 (9.2); **intervention:** 57.9 (9.1)**; comparator:** 57.3 (9.3) **Percentage male: total:** 82.0%; **intervention:** 81.5%;**comparator:** 82.4% **Ethnicity:** European 66.6%; South Asian 10.7%; Other Asian 10.1%; Arab 9.9%; Other 2.7%
Interventions	**Description of intervention:** The text message-based prevention programme involved delivery of regular semi-personalised text messages providing advice, motivation, and information that aimed to improve diet, increase physical activity, and encourage smoking cessation (if relevant). Content for each participant was selected using a prespecified algorithm dependent on key baseline characteristics. Each message was sent on 4 of 5 randomly selected weekdays and arrived at random times of the day during working hours. The general module of messages included information generally provided by secondary prevention programs, e.g. on chest pain action plans, guidelines and risk factor targets, and medications and adherence **Components:** Education **Delivered by:** Text messages (A bank of messages was developed with input from investigators, clinicians, academics, and patients) **Setting (home/centre):** Home **Teaching modalities:** Individual **Involvement of family:** No **Time of start after event:** After discharge **Dose:** **Length of session:** NR **Frequency/number of sessions:** 4 messages per week **Total duration:** 24 weeks. **Follow-up further re-inforcement:** NR **Theoretical basis for intervention:** NR **Co-interventions:** Both groups received 3 study management text messages providing allocation assignment, study contact details, and a reminder before the follow-up appointment **Comparator:** Control participants received usual care, which generally included community follow-up with most referred to inpatient cardiac rehabilitation, as determined

Chow 2015 (*Continued*)

	by their usual physicians **Co-interventions:** Both groups received 3 study management text messages providing allocation assignment, study contact details, and a reminder before the follow-up appointment
Outcomes	Total mortality Withdrawals
Source of funding	National Heart Foundation of Australia Grant-in-Aid and a BUPA Foundation Grant
Conflicts of interest	All authors completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. No conflicts were reported
Notes	NA

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomisation occurred via a computerised randomisation program accessed through a secure web interface
Allocation concealment (selection bias)	Low risk	Randomisation occurred via a computerised randomisation program accessed through a secure web interface
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"…minimizing unblinding at follow-up by sending a message to participants asking them not to disclose their group allocation"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Intervention: 33/352 (9.4%) lost to follow-up Control: 25/358 (7.0%) lost to follow-up
Selective reporting (reporting bias)	Low risk	All outcomes described in the methods were reported
Were groups balanced at baseline?	Low risk	"Baseline characteristics were similar between the groups (Table 1)"
Intention to treat analysis	Low risk	"...and all intervention evaluations were performed on the principle of intention to treat."
Did both groups receive comparable care?	Low risk	Co-interventions were the same in both groups

Clark 1997

Methods	**Study design:** Multicentre RCT (4 sites) **Country:** USA **Dates participants recruited:** NR **When randomised:** NR **Maximum follow up:** 18 months
Participants	**Inclusion criteria: Aged** > 60 years; diagnosed cardiac disease (arrhythmia, angina, MI, valvular disease); treated daily by at least one heart medication; seen by a physician at least once every six months. **Exclusion criteria:** "If physicians felt that they wouldn't be able to benefit fully for the program due to medical reasons (e.g. terminal illness, memory loss, significant hearing loss)" **Recruitment from:** Review of outpatient cardiology clinics in four hospitals in Southern Eastern Michigan **N randomised: total:** 636**; intervention:** NR**; comparator:** NR **Diagnosis (% of pts):** Post MI: 45% Angina: 57% Post CABG: 32% Post PCI: 25% These groups were not mutually exclusive. **Age: mean (range): total:** 69.6 years (60 to 93 years); **intervention:** NR**; comparator:** NR **Percentage male: total:** 59%; **intervention:** 59;**comparator:** 59 **Ethnicity:** 88% white
Interventions	**Description of intervention:** The "Take PRIDE" programme introduces participants to a process for identifying and resolving problems they encounter in managing their heart disease. Participants are asked to follow the following steps: Problem selecting, Researching one's daily routine, Identifying a behavioural goal, Developing a plan to reach one's goal, and Establishing a reward for making progress. Basing decisions on the medical regimens recommended by their physicians, participants select a heart disease management problem to resolve using the PRIDE steps. The common target across subjects is the PRIDE problem-solving process. The intervention aims to enable participants to apply this process to whichever management problem they confront **Components:** Education **Delivered by:** Health educator **Setting (home/centre):** Centre **Teaching modalities:** Videotape, guidebook, interactive group teaching **Involvement of family:** NR **Time of start after event:** Six months to 20 years after initial diagnosis **Dose:** **Length of session:** 2 hours **Frequency/number of sessions:** 4 **Total duration:** 4 weeks **Follow-up further re-inforcement:** NR **Theoretical basis for intervention:** Based on social cognitive theory, particularly the principles of self-regulation (Bandura 1986; Clark and Zimmerman 1990), problem identification, researching one's routine, Identifying a management goal, developing a

	plan to reach it, expressing one's reactions and establishing rewards for making progress **Co-interventions:** NR **Comparator:** Usual care consisted of: "Seeing their physicians at the intervals specified by the particular physician and receiving any information or communications that would be provided as part of routine care in that setting" **Co-interventions:** NR
Outcomes	HRQoL - Sickness Impact Profile Withdrawal from intervention and control group
Source of funding	NR
Conflicts of interest	NR
Notes	NA

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Use of random number table"
Allocation concealment (selection bias)	Low risk	"As the numbers were generated, each was placed in a sealed envelope. They were stored in a locked drawer in my office. As participants completed their baseline interview I was given their names and opened the next envelope in the numerical sequence." Dodge JA (email communication)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Data collectors and data analysts were blinded. The health educators who delivered the intervention obviously knew who had been randomised to the intervention, but had no involvement with the collection of quantitative evaluation data at baseline or follow-up." Dodge JA (email communication)
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	455/636 had complete data at 18/12. "No appreciable difference in dropout rates between the intervention and control groups were found." Similarity of demographic details of those loss to follow up not discussed
Selective reporting (reporting bias)	Low risk	All outcomes listed in the methods are reported in the results

Clark 1997 (*Continued*)

Were groups balanced at baseline?	Low risk	"There were no baseline differences between the experimental and control groups"
Intention to treat analysis	High risk	"Data analyses reported...participants who attended at least one of the four sessions."
Did both groups receive comparable care?	Low risk	Other than the stated intervention both groups appeared to have been treated similarly

Clark 2000

Methods	**Study design:** Multicentre RCT (6 sites) **Country:** USA **Dates patients recruited:** NR **When randomised:** At consent. Median of 13 years since initial cardiac diagnosis (range 6 months to 20 years) **Maximum follow up:** 24 months
Participants	**Inclusion criteria:** > 60 years; female; cardiac disease treated daily with at least one medication; cardiac disease can be arrhythmia, angina, MI or valvular disease **Exclusion criteria:** "If physicians felt they could not benefit fully from the program due to medical reason (e.g. terminal illness or significant hearing loss)" **Recruitment from:** Physician practices affiliated with six medical centres in Southeastern Michigan **N randomised: total:** 570**; intervention:** 309**; comparator:** 261 **Diagnosis (% of pts):** Post MI: 39% Angina: 45% Post CABG: 26% Post PCI: 29% These groups are not mutually exclusive. **Age: mean (range): total:** 71.9 years (range 60 to 93 years); **intervention:** NR**; comparator:** NR **Percentage male: total:** 0%; **intervention:** 0%;**comparator:** 0% **Ethnicity:** 87% white
Interventions	**Description of intervention:** The goal was to enhance overall management of the heart condition by helping older women to be more self-regulating. Adapted from "Take PRIDE" (Clark, Janz, Becker, et al, 1992; Clark et al,1997), participants selected an area of management that was problematic (e.g. exercise, medicine taking, diet). The program recommended a comprehensive approach to managing the heart condition, i.e. using medicines, following dietary recommendations, and exercising. Participants were provided information and assistance to be more self-evaluating and active; e.g. each used a pedometer to log physical activity. During the intervening days, women used a workbook at home as a guide to carrying out the PRIDE steps **Components:** Education

	Delivered by: Trained health educators and peer leaders (selected graduates from the program that received extra training) **Setting (home/centre):** Centre (and home on intervening days) **Teaching modalities:** Class room group sessions (groups of 6 to 8 women). Workbook for use at home on the intervening days. Handouts summarising classroom sessions, daily self-monitoring logs. Weekly telephone call during program period **Involvement of family:** NR **Time of start after event:** NR **Dose:** **Length of session:** 2 to 2.5 hours **Frequency/number of sessions:** weekly (4) **Total duration:** 4 weeks **Follow-up further re-inforcement:** A letter 3 months after program and a telephone call 6 months after **Theoretical basis for intervention:** Yes - PRIDE: Problem identification, Researching one's routine, Identifying a management goal, Developing a plan to reach it, Expressing one's reactions and Establishing rewards for making progress **Co-interventions:** NR **Comparator:** "Usual care": Control group members saw their physicians at the intervals specified by the particular physician and received any information or communications that would be provided as part of routine care in that setting
Outcomes	Total mortality HRQoL - Sickness Impact Profile Adverse events (Withdrawal from intervention group) Hospitalisations (numbers of admissions, inpatient days, hospital inpatient charges) (Wheeler 2003) Cost-effectiveness (Wheeler 2003)
Source of funding	National Heart, Lung, and Blood Institute
Conflicts of interest	NR
Notes	The following paper produced from the results of the same trial were used to inform the data collected: Wheeler 2003

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"...women were assigned, by use of random number tables" (Clark 2000)
Allocation concealment (selection bias)	Unclear risk	NR
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Interviewers were blind to women's participation in the program" (Clark 2000)

Clark 2000 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Table detailing withdrawals
Selective reporting (reporting bias)	Low risk	Outcomes in methods reported in results
Were groups balanced at baseline?	High risk	Demographically similar but statistically significant differences in baseline disease symptoms and weight
Intention to treat analysis	Low risk	Data was analysed in two different phases, one "an analysis of all women randomised" the other "all program women who attended one or more program sessions" (Clark 2000)
Did both groups receive comparable care?	Low risk	"In an effort to assure similar care to both the program and the control groups, no feedback about individual participants was provided to medical or nursing staff. The clinical staff had no knowledge of which patients had agreed to participate in research" (Clark 2000)

Clark 2009

Methods	**Study design:** Multicentre RCT - 3 groups **Country:** USA **Dates patients recruited:** N/A - list compiled from physicians patient rota **When randomised:** After collecting baseline data **Maximum follow up:** 18 months
Participants	**Inclusion criteria: Aged** > 60 years; diagnosed cardiac condition (arrhythmia, angina, MI, congestive heart failure, valvular disease); treated by daily heart medication; seen by a physician in the last year; living within 1 hour drive of the study site **Exclusion criteria:** If not able to fully participate because of medical reasons **Recruitment from:** Five hospital sites in Southeastern Michigan **N randomised: total:** 575**; intervention:** Self Directed: 201; Group Format:190**; comparator:** 184 **Diagnosis (% of pts):** Post MI: 42% Angina: 38% Post CABG: NR Post PCI: NR These groups are not mutually exclusive. **Age: mean (range): total:** 72.8 years (60 to 90 years); **Group:** 73.1 years (61 to 87 years) ; **Self-directed:** 72.7 years (61 to 88 years);**comparator:** 72.5 years (60 to 90 years) **Percentage male: total:** 0% **Ethnicity:** 82.8% white

Interventions	**Description of intervention:** Comparison of a "Take PRIDE" - based intervention, delivered in (i) self-directed and (ii) group formats.The content of and the materials used with the two formats were the same. Both formats consisted of six units. Both groups received weekly telephone calls from a heath educator during the study period. The self directed group also had an instructional video tape that gave examples of group discussions The content (instructor's manual,videotape, workbook and logs) was tailored to the unique roles, responsibilities and settings in which older women manage their heart disease. In the self-directed format, women engage in the same self regulatory process at home in their own timeframe, while the group format women meet for 2-2 1/2 hours on a weekly basis. In the self-directed version, motivation and support that are part of the social environment in the group format are provided via an instructional videotape that presents examples of group discussions. Weekly telephone calls from a health educator or a peer leader are also provided **Components:** Education **Delivered by:** Trained health educators and peer leaders **Setting (home/centre):** Single orientation session at centre then home **Teaching modalities:** Groups of 6 to 8 women **Involvement of family:** NR **Time of start after event:** NR **Dose:** **Length of session:** 2 to 2.5 hours **Frequency/number of sessions:** 6 weekly sessions **Total duration:** 6 weeks **Follow-up further re-inforcement:** Participants in both formats received a monthly newsletter for three months following completion of their program. At six months, the group format women wee invited to attend a reunion and the self-directed participants received an in-depth motivational telephone call from the health educator **Theoretical basis for intervention:** Yes, described in separate paper **Co-interventions:** NR **Comparator:** Usual care: "see their physician on the routine schedule and receive any information that would normally be provided as part of regular care in the practice." **Co-interventions:** NR
Outcomes	Total mortality HRQoL - Sickness Impact Profile (SIP) Withdrawal from treatment
Source of funding	Heart Division of the National Heart, Lung, and Blood Institute
Conflicts of interest	NR
Notes	NA

Risk of bias

Bias	Authors' judgement	Support for judgement

Clark 2009 (*Continued*)

Random sequence generation (selection bias)	Low risk	"...complied using...book of random numbers."
Allocation concealment (selection bias)	Low risk	"Sealed opaque and sequentially numbered envelopes."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Those assessing outcomes were blinded to the group allocation unless the participant happened to reference program participation during the follow-up telephone interviews or at the physical assessment visit." Correspondence with author, J Dodge
Incomplete outcome data (attrition bias) All outcomes	Low risk	Clear description of withdrawals from trial given
Selective reporting (reporting bias)	Low risk	Sickness Impact Profile numerical scores were not individually reported as no significant difference was found. These were subsequently made available through correspondence with author, J Dodge
Were groups balanced at baseline?	Low risk	"no significant differences among study conditions..." (Table 1)
Intention to treat analysis	Low risk	"Analyses were carried out using the women as they were randomised to each of the three study conditions"
Did both groups receive comparable care?	Low risk	"In an effort to ensure similar care to all participants, no feedback about individual study participants was provided to health care personnel at the study sites."

Cohen 2014

Methods	**Study design:** Multicentre RCT (6 sites) **Country:** France **Dates patients recruited:** June 21 2006 to July 30 2008 **When randomised:** During their hospitalisation **Maximum follow up:** 1 year
Participants	**Inclusion criteria:** At least 18 years of age, were hospitalised in a cardiac intensive care unit for an ACS (unstable angina, ST-segment elevation MI, or non-ST-segment elevation MI), and had at least 1 of the following education modifiable risk factors: current smoking (for ≥ 12 months), sedentary lifestyle (< 3 hours of physical activity per week), or overweight or obesity (body mass index ≥ 25 for overweight or ≥ 30 for obesity, calculated as weight in kilograms divided by height in meters squared). Patients

	also had to be willing and able to attend regular visits at an outpatient program **Exclusion criteria:** NR **N Randomised: total:** 502**; intervention:** 251**; comparator:** 251 **Diagnosis (% of pts):** ST elevation MI: intervention: 48.8%; comparator: 47.0% Non-ST-elevation MI: intervention: 35.2%; comparator: 32.9% Unstable angina: intervention:16.0%; comparator:20.1% **Age (mean ± SD): total:** NR; **intervention:** 58.0 years (± 10.9 years)**; comparator:** 55.7 years (± 10.9 years) **Percentage male: total:** NR; **intervention:** 80.9%;**comparator:** 87.6% **Ethnicity:** NR
Interventions	**Description of intervention:** Patients attended the House of Education at least 6 times: within the first month after discharge and then at months 2, 3, 6, 9, and 12. Patients could attend additional consultations at any time up to 12 months after the index event. The content of the consultations was individualised according to a patient's risk factors. Current smokers attended a consultation with the nurse specialised in the management of smoking cessation. The consultation with the dietician comprised an evaluation of the patient's diet, followed by an explanation of the general principles for an adequately balanced diet **Components:** Education **Delivered by:** Nurse who was specialised in smoking cessation counselling, and a dietician who had received training in physical activity counselling **Setting (home/centre):** Centre **Teaching modalities:** Individual **Involvement of family:** A consultation with the patient's partner could be organised to improve the patient's diet **Time of start after event:** Within a month after discharge **Dose:** **Length of session:** NR **Frequency/number of sessions:** At least 6 times **Total duration:** 12 months **Follow-up further re-inforcement:** Information related to the hospitalisation period, the patient's risk factors, and objectives for risk factor management was recorded via the Internet system. An e-mail was automatically sent to the staff at the House of Education and to the primary care physicians (general practice and cardiologists). The staff and the primary care physicians could log into the system using a secure access to see all patient information **Theoretical basis for intervention:** NR **Co-interventions:** Information was recorded on the prescription of co-interventions (e.g. nicotine supplements, hospitalisation in a rehabilitation centre, and others). The administration was left to the discretion of the care provider **Comparator:** Patients in the control group attended appointments with their primary care physician and primary care cardiologist within 1 month of discharge **Co-interventions:** Information was recorded on the prescription of co-interventions (e.g. nicotine supplements, hospitalisation in a rehabilitation centre, and others). The administration was left to the discretion of the care provider

Outcomes	Total mortality Withdrawals HRQoL
Source of funding	The study was funded by grant 960 110 211 from the Unions Régionales des Caisses d'Assurance Maladie
Conflicts of interest	Dr Cohen has received a research grant for research nurses (RESICARD) and consultant and lecture fees from AstraZeneca, Bayer Pharma, Bohringer-Ingelheim, Daiichi Sankyo, GlaxoSmithKline, and sanofi-aventis. Dr Solol has received grants and honorarium from Servier, Roche, Pfizer, Bayer Pharma, Novartis, Alere, Thermofischer, sanofi-aventis, Ipsen, and Vifor. Dr Montalescot has received research grants to the institution or consultant and lecture fees from Bayer Pharma, Bristol-Myers Squibb, Boehriinger-Ingelheim, Duke Institute, Europa, GlaxoSmithKline, Iroko, Lead-Up, Novartis, Springer, TIMI group, WebMD, Wolters, AstraZeneca, Biotronik, Eli Lilly, The Medicines Company, Medtronic, Menarini, Roche, sanofi-aventis, Pfizer, Accumetrics, Abbott Vascular, Daiichi Sankyo, Fédération Française de Cardiologie, Fondation de France, INSERM, Institut de France, Nanosphere, Stentys, and Société Française de Cardiologie. Dr Steg has received research grants from New York University School of Medicine, Servier, and sanofi-aventis. He has served as a speaker or consultant to Ablynx, Amarin, Amgen, Astellas, AstraZeneca, Bayer Pharma, Boehringer-Ingelheim, Bristol-Myers Squibb, Daiichi Sankyo, Eisai, GlaxoSmithKline, Eli Lilly, Medtronic, Merck-Sharpe Dohme, Novartis, Otsuka, Pfizer, Roche, sanofi-aventis, Servier, The Medicines Company, and Vivus. He has equity ownership in Aterovax. No other disclosures were reported
Notes	NA

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Patients were randomised according to a computer-generated list with blocks of varying size stratified on centers"
Allocation concealment (selection bias)	Low risk	"The list was prepared and maintained by an independent statistician at the clinical trial unit. Allocation was concealed in sequentially numbered, sealed opaque envelopes."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	" independent research staff rather than the treating physician performed outcome assessments."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Intervention: 48/251 (19.1 %) lost to follow-up Control: 36/251 (14.3 %) lost to follow-up

Cohen 2014 (*Continued*)

Selective reporting (reporting bias)	Low risk	All outcomes described in methods are reported
Were groups balanced at baseline?	Low risk	Baseline characteristics for patients in the 2 treatment groups were well balanced (Table 1)
Intention to treat analysis	Low risk	"The primary end point was analysed according to the intent-to-treat principle."
Did both groups receive comparable care?	Low risk	Co-interventions received by the two groups were similar (e.g. nicotine supplements, hospitalisation in a rehabilitation centre, and others)

Cupples 1994

Methods	**Study design:** Multicentre RCT (18 sites) **Country:** Northern Ireland, UK **Dates patients recruited:** between 1990 and 1993 **When randomised:** NR **Maximum follow up:** 5 years
Participants	**Inclusion criteria:** ≥ 6 month history of angina diagnosed by classical history **Exclusion criteria:** No other severe illness **Recruitment from:** 18 general practices in Greater Belfast **N randomised: total:** 688**; intervention:** 342**; comparator:** 346 **Diagnosis (% of pts):** Angina: 100% Previous MI: 45% **Age (mean ± SD): total:** NR; **intervention:** 62.7 years (7.1) **; comparator:** 63.6 years (6.8) **Percentage male: total:** 59.3%; **intervention:** 59.4%;**comparator:** 59.2% **Ethnicity:** NR
Interventions	**Description of intervention:** "Patients in the intervention group were given practical relevant advice regarding cardiovascular risk factors. They were reviewed at four monthly intervals and given appropriate health education (Cupples 1994)." "Visited by a health visitor, whose brief was to discuss ways of living more easily with their disease and ways in which risks of further events might be reduced (O'Neill 1996)." "The education involved giving information which was tailored to the individuals' coronary risk factors and the use of medication (Cupples 1996)" **Components:** Education **Delivered by:** Health visitor **Setting (home/centre):** NR **Teaching modalities:** Individual one-to-one visits

	Involvement of family: NR **Time of start after event:** NA **Dose:** **Length of session:** NR **Frequency/number of sessions:** 6 visits (every 4 months for 2 years) **Total duration:** 2 years **Follow-up further re-inforcement:** Not following 2 year intervention **Theoretical basis for intervention:** NR **Co-interventions:** NR **Comparator:** Patients in the usual care group received the same screening interview as the intervention group but once randomised to control had no further intervention **Co-interventions:** NR
Outcomes	Total mortality Cardiovascular related mortality Hospitalisations recorded as part of cost analysis (not independently reported) (O'Neill 1996) HRQoL (Nottingham Health Profile Questionnaire) (Cupples 1996) Adverse events (withdrawal from intervention group) Cost Analysis (O'Neill 1996)
Source of funding	The Medical Research Council
Conflicts of interest	NR
Notes	The following papers produced from the results of the same trial were used to inform the data collected: Cupples 1996; Cupples 1999; O'Neill 1996

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"generated by a computer program using permuted blocks (Cupples 1996)."
Allocation concealment (selection bias)	Low risk	"The health visitor opened an opaque, sealed, and numbered envelope containing the allocation" (Cupples 1994)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"After 2 years both groups were reviewed by a research worker who had not previously been involved with the subjects" (Cupples 1994) At five year follow-up: "nurse (performing interview) was blind to trial group allocation" (Cupples 1999)

Cupples 1994 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Detailed report of withdrawals and losses to follow up reported Cupples 1994 Yes; Cupples 1996 No; O'Neill 1996 No; Cupples 1999 No
Selective reporting (reporting bias)	Low risk	All relevant outcomes listed in methods were reported in methods
Were groups balanced at baseline?	Low risk	"No significant differences were found between the two groups at baseline" (Cupples 1994)
Intention to treat analysis	Low risk	*"We also analysed the data in an intention to treat basis, with baseline or adjusted values being substituted for missing data, but this did not alter the conclusions* (Cupples 1999) ."
Did both groups receive comparable care?	Low risk	Both groups received same usual care and only difference between groups was the educational intervention

Dracup 2009

Methods	**Study design:** Multicentre RCT (18 sites) **Country:** USA, Australia and New Zealand **Dates patients recruited:** Between 2002 and 2004 **When randomised:** Following collection of baseline data **Maximum follow up:** 2 years
Participants	**Inclusion criteria:** Diagnosis of ischemic heart disease, confirmed by their physician or hospital medical record, and if they lived independently (i.e. not in an institutional setting) **Exclusion criteria:** Patients were excluded if they had any of the following: complicating serious co-morbidity such as a psychiatric illness or untreated malignancy, neurological disorder with impaired cognition, or inability to read or understand English **N Randomised: total:** 3522**; intervention:** 1777**; comparator:** 1745 **Diagnosis (% of pts):** ACS (100%) **Age (mean ± SD): total:** 67 ± 11 years; **intervention:** NR**; comparator:** NR **Percentage male: total:** 68.0%; **intervention:** 66.2%;**comparator:** 69.7% **Ethnicity:** 91.1% white
Interventions	**Description of intervention:** Patients received education in three areas: information about ACS, anticipated emotional issues and social factors that could affect delay. Patients were given standardised information about typical and atypical symptoms of ACS and possible variability in symptom presentation. Patients were told that they might experience chest pressure or discomfort that was intermittent rather than constant, and

	that diaphoresis, shortness of breath, and pain radiation to parts of the body other than the left arm (e.g. neck or back) were also possible symptoms of ACS. They were advised to call emergency medical services immediately. Patients were asked to anticipate the emotional responses to ACS symptoms that might lead to delay, as well as to discuss their previous experiences accessing the medical system. The rewards of seeking treatment immediately were emphasised and emotional issues were addressed through role playing scenarios that were standardised across intervention group patients. The potential reaction of the family member was discussed (e.g. denial, fear, ambivalence, etc.) and the importance of and rewards for quick action were underscored **Components:** Education and counselling **Delivered by:** A nurse with expertise in cardiology **Setting (home/centre):** Home or centre **Teaching modalities:** Individual **Involvement of family:** Patients were asked to bring their spouse, another family member or friend to the intervention session whenever possible. These individuals were "deputised" to act as the decision maker if the patient hesitated to call emergency medical services **Time of start after event:** NR **Dose:** **Length of session:** 40 minutes **Frequency/number of sessions:** 1 **Total duration:** 55 minutes (40 min plus 15 min follow-up call) **Follow-up further re-inforcement:** One month following the initial intervention session, the nurse who had provided the intervention called each patient and reviewed the main points from the initial session. The average length of the phone call was 15 minutes **Theoretical basis for intervention:** Based on Leventhal's self regulatory model of illness behaviour **Co-interventions:** At the time of the development of the educational intervention, patients who had no contraindications were encouraged to take one non-enteric coated aspirin prior to arrival at the hospital as well as nitroglycerin (if prescribed), and this instruction was included **Comparator:** Usual care **Co-interventions:** NR
Outcomes	Total mortality Hospitalisations Withdrawals
Source of funding	National Institutes of Health, National Institute of Nursing Research
Conflicts of interest	No real or perceived conflicts of interest exist for any of the authors of this manuscript
Notes	NA

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Dracup 2009 (*Continued*)

Random sequence generation (selection bias)	High risk	Method of randomisation not described
Allocation concealment (selection bias)	High risk	Method of allocation concealment not described
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Physicians caring for patients and nurses collecting follow-up data were blinded to study assignment."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Intervention: 197/1777 (11.1%) lost to follow-up Control: 238/1745 (13.6%) lost to follow-up
Selective reporting (reporting bias)	Low risk	All outcomes described in the methods are described in the results
Were groups balanced at baseline?	High risk	"A check on randomisation revealed no significant differences between groups on a variety of demographic and clinical variables except for body mass index (P = 0.048), gender (with more females in the experimental group than control, P = 0.02), and insurance for ambulance use (with more patients with insurance in the control group compared to the experimental group, P = 0.04) (Table 1)."
Intention to treat analysis	High risk	ITT analysis is not described and data from patients lost to follow-up are not included in analyses
Did both groups receive comparable care?	High risk	Intervention included counselling

Esposito 2008

Methods	**Study design:** Multicentre RCT **Country:** USA **Dates patients recruited:** All Florida Medicare beneficiaries enrolled in Medicaid as of March 2006 who met eligibility criteria **When randomised:** "When eligible beneficiaries are identified." **Maximum follow up:** 18 months
Participants	**Inclusion criteria:** Enrolled in Medicare and receiving Medicard benefits; have congestive cardiac failure, diabetes or CAD **Exclusion criteria:** Psychiatric inpatient therapy of more than 14 consecutive days in the prior 12 months; long term nursing home residence

	Recruitment from: Medicare database **N Randomised: total:** 46,606**; intervention:** 33,267**; comparator:** 13,339 **Diagnosis (% of pts):** CAD (Not further defined): 69% In combination with heart failure: 10% In combination with diabetes: 19% With all three diagnoses: 12% **Age (mean): total:** 68.4 years; **intervention:** 68.4 years**; comparator:** 68.4 years **Percentage male: total:** 34%; **intervention:** 34%;**comparator:** 34% **Ethnicity:** 55% white
Interventions	**Description of intervention:** "Nurse case managers provided education to patients on the recognition of signs and symptoms of their disease; how to monitor vital signs; the cause of diseases; how to better adhere to diet, exercise, and medication regimes; and strategies to cope with chronic illness. When providing education to patients, nurses use pre-designed scripts. Geared towards educating patients on how to attain clinical goals." **Components:** Education **Delivered by:** Individually assigned nurse care manager **Setting (home/centre):** Home (telephone) **Teaching modalities:** "The intervention is primarily telephonic, but also had an in-person component." **Involvement of family:** NR **Time of start after event:** NA **Dose:** Patients received 1.1 contacts per active month, on average **Length of session:** NR **Frequency/number of sessions:** NR **Total duration:** 18 months **Follow-up further re-inforcement:** Intervention continued until end of follow up period **Theoretical basis for intervention:** NR **Co-interventions:** Patient assessment, care planning, routine nurse monitoring, patient self-monitoring, care co-ordination, and service arrangement **Comparator:** Not described **Co-interventions:** NR
Outcomes	Hospitalisations - Emergency and inpatient use HRQoL (survey of selected 613 enrollees only and claims based quality of care measures) Cost analysis
Source of funding	NR
Conflicts of interest	"The authors are with Mathematica Policy Research, Inc. The statements expressed in this article are those of the authors and do not necessarily reflect the views or policies of Mathematica Policy Research, Inc., or the Centers for Medicare & Medicaid Services (CMS)."
Notes	Analysed first and second 6 month periods, first year and 18 months Population based study that only a relatively small proportion of those assigned to the intervention group actually actively continued to participate in. Therefore treatment

Esposito 2008 (*Continued*)

	effect may be difficult to statistically demonstrate

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	NR
Allocation concealment (selection bias)	Unclear risk	NR
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	NR
Incomplete outcome data (attrition bias) All outcomes	Low risk	Divided patients in to mediated - those that fully engaged with the intervention and instructional - those that were less that fully engaged but did not opt out. Breakdown of mediated patients demonstrated in a table
Selective reporting (reporting bias)	Low risk	Primary outcomes stated in methods were reported in the results
Were groups balanced at baseline?	Low risk	Detailed table (Table 4) of pre-enrolment characteristics showed no statistically significant differences seen. Authors reported that there was a difference in that the treatment group utilised health services 5% more in 2 year run up period to the trial (not statistically significant)
Intention to treat analysis	Low risk	"intention to treat study design."
Did both groups receive comparable care?	High risk	Education only part of the intervention: "intervention components include patient assessment, care planning, routine nurse monitoring, patient self-monitoring, education, care co-ordination, and service arrangement." Physicians were alerted to "important changes in patients' health."

Furuya 2015

Methods	**Study design:** Single centre RCT **Country:** Brazil **Dates patients recruited:** August 2011 to June 2012 **When randomised:** After collecting baseline data **Maximum follow up:** 6 months
Participants	**Inclusion criteria:** Aged 18 years or older, undergoing first PCI and had access to a telephone **Exclusion criteria:** Exclusion criteria included: being clinically unable to answer questions or talk on the telephone (e.g. patients with dyspnea, confusion or unable to hear) ; having sequelae affecting daily activities (e.g. amputation or paresis); being already enrolled in another educational programme; or having cognitive impairment as assessed by the Mini-Mental State Examination (MMSE) adapted to the Brazilian population (Brucki et al. 2003) **N randomised: total:** *66**; intervention:** 34**; comparator:** 32 **Diagnosis (% of pts):** PCI: 100% **Age (mean ± SD): total:** NR; **intervention:** 63.3 years (± 12.4)**; comparator:** 60.6 years (± 8.7) **Percentage male: total:** %; **intervention:** 60.0%;**comparator:** 53.3% **Ethnicity:** NR
Interventions	**Description of intervention:** The educational programme consisted of three booklets and three telephone follow-up calls.The first booklet was discussed with participants before undergoing PCI procedure. The objective was to help the patient to understand his cardiac condition, the PCI procedure and how to cope with CAD in general. The other two booklets focused on self-care related to the PCI itself and to day-to-day management of the disease, which were discussed with participants after PCI, on the day of procedure or on the following day. Three telephone calls were made (in the first, eighth and sixteenth week after hospital discharge), focusing on lifestyle changes. The telephone script contained questions on self-care including: care of arm and leg used for the PCI procedure, changes in risk factors for CAD and correct use of medication. Each participant was asked whether s/he was successfully executing changes in physical activity, eating and smoking habits and verifying blood pressure. Then the investigator attempted to motivate the participant to make behavioural changes and discussed barriers to changing habits **Components:** Education **Delivered by:** Two researchers **Setting (home/centre):** Centre **Teaching modalities:** Individual **Involvement of family:** NR **Time of start after event:** Programme commenced prior to PCI procedure **Dose:** **Length of session:** NR **Frequency/number of sessions:** 2 face-to-face sessions and 3 telephone calls **Total duration:** 16 weeks **Follow-up further re-inforcement:** Each participant was instructed to make a telephone call to the investigator for further questions or support for secondary prevention for CAD

Furuya 2015 (*Continued*)

	Theoretical basis for intervention: Based on the construct of self-efficacy according to Albert Bandura's Social Cognitive Theory (Bandura 2004) **Co-interventions:** NR **Comparator:** Control group participants received the usual instructions given by health-care providers at the hospital **Co-interventions:** NR
Outcomes	HRQoL Withdrawals
Source of funding	Grants 2010/19761-3 and 2010/10006-8, São Paulo Research Foundation (FAPESP)
Conflicts of interest	The authors state that there are no financial and personal relationships with people or organisations that could inappropriately influence this work
Notes	*90 Patients were originally randomised but 24 were excluded after randomisation for the following reasons: further medical assessment indicated need for surgical revascularisation or clinical treatment (N = 20), or participant was enrolled in another educational programme (N = 4)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"A research staff member...generated the random allocation in Graphpad software"
Allocation concealment (selection bias)	Low risk	A research staff member…generated the random allocation in Graphpad software…concealing it from the investigators in sequentially numbered, sealed, opaque envelopes."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Therefore, investigators who were unblinded to participant allocation helped with the data collection."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Intervention: 4/34 (11.8%) lost to follow-up Control: 2/32 (6.3%) lost to follow-up (90 participants were originally randomised (45 in each group), but 24 participants were excluded immediately after randomisation as they were indicated for surgery or enrolled in another study)
Selective reporting (reporting bias)	Low risk	All outcomes described in the methods are reported

Furuya 2015 (*Continued*)

Were groups balanced at baseline?	Low risk	"The intervention and control groups did not differ significantly in socio-demographic and clinical characteristics at baseline (P > 0.12 for all variables)."
Intention to treat analysis	High risk	No ITT analysis is described and data from patients lost to follow-up are not included in the analyses
Did both groups receive comparable care?	Low risk	Neither group received any co-interventions other than medication

Hanssen 2007

Methods	**Study design:** Single centre RCT **Country:** Norway **Dates patients recruited:** Sept 2001 to Sept 2005 **When randomised:** After hospitalisation of at least 2 days **Maximum follow up:** 18 months
Participants	**Inclusion criteria:** All patients with confirmed AMI and admitted to the hospital. **Exclusion criteria:** Severe co-existing chronic disabling disease; nursing home resident; unable to receive telephone calls; unable to fill in questionnaires; if expected to have CABG in that admission; In the first year of the study > 80 year olds were excluded, after the first year they were included **Recruitment from:** Haukeland University Hospital, Bergen, Norway **N randomised: total:** 288**; intervention:** 156**; comparator:** 132 **Diagnosis (% of pts):** Post MI: 100% **Age (mean ± SD): intervention:** 59.5 years (12.9)**; comparator:** 60.9 years (10.8) **Percentage male: total:** 81%; **intervention:** 84.6%;**comparator:** 76.5% **Ethnicity:** NR
Interventions	**Description of intervention:** "Structured intervention encompassing telephone follow up and an open telephone line" "to provide patients with information, education and support on the basis of individual needs. To provide patients with information about what are common questions after AMI and encourage elaboration on the issues if desired. One issue was addressed in each call." **Components:** Education and counselling **Delivered by:** Nurses with interests and experience in counselling and providing information to patients with ischaemic heart disease **Setting (home/centre):** Home (telephone) **Teaching modalities:** Telephone follow up **Involvement of family:** (telephone) "Lines were open to patients and relatives/relations" **Time of start after event:** On discharge following the event **Dose:** **Length of session:** As long as required (mean telephone call 6.88 min (SD 3.89)) **Frequency/number of sessions:** 8 (weekly first 4 weeks, then weeks 6, 8, 12 and 24).

	Total duration: 6 months (could stop earlier if requested) but encouraged to have at least the first 5 months intervention **Follow-up further re-inforcement:** None **Theoretical basis for intervention:** Intervention was developed on the basis of the Lazarus and Folkmans theory on stress, appraisal and copy, principles about patient education, findings from previous research and according to guideline recommendations **Co-interventions:** Counselling **Comparator:** Managed in accordance with current clinical practice. Included one visit to a physician at the outpatient clinic 6 to 8 weeks after discharge, and subsequent visits to the patient's general practitioner **Co-interventions:** NR
Outcomes	HRQoL (SF-36) Re-admission to hospital Mortality
Source of funding	Haukeland University Hospital, the Norwegian Nurse Association, the Meltzer Foundation for grants, and the Norwegian Lung and Heart Foundation
Conflicts of interest	"None"
Notes	The following paper produced from the results of the same trial were used to inform the data collected: Hanssen 2009

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"A simple randomisation procedure using a computer-generated list of random numbers"
Allocation concealment (selection bias)	Low risk	"...group allocation in sealed opaque envelopes prepared by the researcher."
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not clear if researchers were blinded to group allocations
Incomplete outcome data (attrition bias) All outcomes	Low risk	CONSORT diagram of trial flow reported with details of withdrawals and loss to follow up
Selective reporting (reporting bias)	Low risk	Outcomes in methods reported in results.
Were groups balanced at baseline?	Low risk	"No statistically differences were found" in baseline characteristics

Hanssen 2007 (*Continued*)

Intention to treat analysis	Low risk	Although intention to treat analysis not explicitly stated, the groups were analysed according to original random allocation
Did both groups receive comparable care?	High risk	Intervention included both education and counselling - psychological based intervention. "Providing emotional support and alternative coping strategies" which was not received by control group

Jorstad 2013

Methods	**Study design:** Multicentre RCT (11 sites) **Country:** Netherlands **Dates patients recruited:** June 2006 to July 2009 **When randomised:** Shortly after hospitalisation **Maximum follow up:** 12 months
Participants	**Inclusion criteria:** Patients aged 18 to 80 years were eligible if they had been diagnosed with an ACS (STEMI, non-STEMI or unstable angina pectoris), within 8 weeks prior to entry into the study **Exclusion criteria:** Visits to the nurse coordinated prevention programmes not feasible; not available for follow-up; surgery, percutaneous coronary intervention or other interventions expected within 8 weeks after inclusion; limited life expectancy (≤2 years) ; previously enrolled in the nurse coordinated prevention programme; New York Heart Association class III or class IV heart failure **N randomised: total:** 754**; intervention:** 375**; comparator:** 379 **Diagnosis (% of pts):** STEMI: **intervention:** 50%; **comparator:**48% NSTEMI: **intervention:** 33%; **comparator:**33% Unstable angina pectoris: **intervention:** 17%; **comparator:** 19% **Age (mean ± SD): total:** NR; **intervention:** 57.5 ± 9.9**; comparator:** 57.8 ± 10.4 **Percentage male: total:** 80%; **intervention:** 80%;**comparator:** 80% **Ethnicity:** NR
Interventions	**Description of intervention:** The programme included four outpatient clinic visits to a cardiovascular nurse during the first 6 months: at weeks 2, 7, 12 and 17 after baseline. The nurse-coordinated prevention programme followed a protocol based on national and international guidelines, focusing on (1) healthy lifestyles, (2) biometric risk factors and (3) medication adherence. During each visit, smoking status, dietary status, level of physical exercise, weight, waist circumference, blood pressure, total cholesterol, high-density lipoprotein (HDL) cholesterol, low density lipoprotein (LDL) cholesterol, triglycerides, glucose and HbA1c were reviewed. Nurses provided general lifestyle advice, including dietary advice. Nurses provided specific educational material and individual counselling to achieve smoking cessation, adequate physical exercise and healthy weight/ fat distribution. There were no visits to the nurse-coordinated prevention programme between 6 and 12 months **Components:** Education

	Delivered by: Registered nurses with a 4-year bachelor's degree and experience in the care of cardiac patients. All nurses were given a 3-day course in motivational interviewing **Setting (home/centre):** Centre **Teaching modalities:** NR **Involvement of family:** NR **Time of start after event:** 2 weeks **Dose:** **Length of session:** NR **Frequency/number of sessions:** 4 sessions **Total duration:** 6 months **Follow-up further re-inforcement:** NR **Theoretical basis for intervention:** NR **Co-interventions:** Adherence to prescribed medication was encouraged at each visit, including antithrombotic therapy and a statin. If discontinued, reasons for discontinuation were documented, and if possible the therapy was restarted **Comparator:** Usual care included outpatient clinic visits to treating cardiologists and other relevant specialists. This included referral to cardiovascular rehabilitation according to the national guidelines on cardiovascular rehabilitation. In short, cardiovascular rehabilitation typically consisted of a 12 week programme of evaluation of physical, psychological and social functioning, of providing education, physical exercise, and interventions to improve physical and social functioning and to improve cardiovascular risk factors and/or risk behaviour. Cardiologists were encouraged, in all patients, to adhere to current national and international guidelines for secondary prevention of cardiovascular disease **Co-interventions:** As above
Outcomes	Total mortality Hospitalisations Withdrawals
Source of funding	The study was sponsored by an unrestricted grant from AstraZeneca, The Netherlands. The sponsor had no role in the design, data collection, data analysis, data interpretation and writing of this report
Conflicts of interest	None
Notes	NA

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The online randomisation protocol consisted of a pre-generated block-stratified randomisation protocol"
Allocation concealment (selection bias)	Low risk	"Study personnel entered patient's initials, date of birth and gender, and participating individuals were assigned a study identifi-

Jorstad 2013 (*Continued*)

		cation number along with their allocation to either the intervention group or control group."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"The randomly assigned treatment of patients was not disclosed to treating cardiologists or general practitioners."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Intervention: 23/375 (6.1%) lost to follow-up Control: 35/379 (9.2%) lost to follow-up
Selective reporting (reporting bias)	Low risk	All outcomes described in the methods are reported
Were groups balanced at baseline?	Low risk	All characteristics and prognostic factors were similar in both groups at baseline
Intention to treat analysis	High risk	ITT analysis is not described, and data from patients lost to follow up are not included in the analyses
Did both groups receive comparable care?	Low risk	"Patients were randomised to either the nurse-coordinated prevention programme in addition to usual care (intervention group) or usual care alone (control group)."

Lie 2009

Methods	**Study design:** Single centre RCT **Country:** Norway **Dates patients recruited:** August 2003 to 2004 **When randomised:** NR **Maximum follow up:** 6 months
Participants	**Inclusion criteria:** All elective CABG patients aged 18 to 80 years **Exclusion criteria:** More than 3 hours driving distance **Recruitment from:** Hospital **N randomised: total:** 203**; intervention:** 101**; comparator:** 102 **Diagnosis (% of pts):** Post CABG: 100% Previous AMI: **intervention**: 40%; comparator: 31% **Age mean (range): total:** 62 years; **intervention:** 62 years (39 to 77 years); **comparator:** 62 years (42 to 78 years) **Percentage male: total:** 89.5%; **intervention:** 90%;**comparator:** 89% **Ethnicity:** NR

Lie 2009 (*Continued*)

Interventions	**Description of intervention:** Structured information and psychological support for the topics of angina symptoms, medications, sexuality, anxiety, and depression. Material developed for the study **Components:** "A psycho-educative intervention" **Delivered by:** Masters prepared critical care nurse with 12 years' experience **Setting (home/centre):** Home **Teaching modalities:** Home visits **Involvement of family:** NR **Time of start after event:** 2 weeks post CABG **Dose:** **Length of session:** 1 hour **Frequency/number of sessions:** 2 **Total duration:** 4 weeks **Follow-up further re-inforcement:** No **Theoretical basis for intervention:** NR **Co-interventions:** Psychological support **Comparator:** Patients in the intervention group and the control group received standard discharge care that involved a non-standardised short talk with the nurse/doctor **Co-interventions:** NR
Outcomes	HRQoL - SF36 and Seattle Angina Questoinnaire (SAQ)
Source of funding	NR
Conflicts of interest	NR
Notes	NA

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Statistician made the randomisation codes by using a computer program."
Allocation concealment (selection bias)	Low risk	"...a secretary created sealed opaque envelopes containing individual codes with sequential numbers."
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding not described
Incomplete outcome data (attrition bias) All outcomes	Low risk	Clear table demonstrating patients excluded and the attrition. All accounted for at the end of the trial Minimal incomplete data from responses in each group in both questionnaires e.g. "number of respondents for each subscale

Lie 2009 (*Continued*)

		and each measurement point ranged between 74 and 92 for each group“
Selective reporting (reporting bias)	Low risk	All stated outcomes SAQ and SF-36 at 6 months reported
Were groups balanced at baseline?	Low risk	Baseline characteristics ”did not differ significantly between groups“
Intention to treat analysis	Low risk	ITT not explicitly stated. Reported patient flow chart suggests that groups analysed according to original random allocation
Did both groups receive comparable care?	High risk	”Patients in the intervention group and the control group received standard discharge care that involved a non-standardised short talk with the nurse/doctor.“ However, the intervention contained psychological support which was not delivered to the control group

Lisspers 1999

Methods	**Study design:** Single centre RCT **Country:** Sweden **Dates patients recruited:** Feb 1993 and Dec 1995 **When randomised:** NR **Maximum follow up:** 60 months
Participants	**Inclusion criteria:** At least one coronary stenosis suitable for PCI and at least one additional clinically insignificant coronary artherosclerotic lesion that could be evaluated by quantitative computerised angiography; employed; able to perform bike test **Exclusion criteria:** Absence of other disease that would prevent completion of programme**;** age > 65 years; unemployed **Recruitment from:** Consecutive referrals to cardiology outpatients of 1 hospital **N randomised: total:** 87**; intervention:** 46**; comparator:** 41 **Diagnosis (% of pts):** Post PCI: 100% Previous MI: **intervention**: 43%; **comparator**: 32% Congestive heart failure: **intervention**: 9%; **comparator**: 5% **Age (mean ± SD): total:** 53 ± 7 years; **intervention:** 53 ± 7 years**; comparator:** 53 ± 7 years **Percentage male: total:** 83.9%; **intervention:** 80.4%;**comparator:** 87.8% **Ethnicity:** NR
Interventions	**Description of intervention:** Intervention had a duration of 12 months, and started with a 4-week residential stay at the intervention unit. This first phase consisted of intense health education and behaviour-change activities, including lectures and discus-

	sions, but focusing mainly on practical skills training and habit rehearsal directed toward stress management and diet, exercise, and smoking habits. Much of the education, discussions, and introductory skills training in the different lifestyle areas were performed. The curriculum included regular group-based practical skills training sessions in all areas; e.g. physical exercise,food preparation, biofeedback, and training in applied relaxation. The participants were also assigned daily "homework," to be performed individually (or sometimes in groups) between the group sessions **Components:** Education and behaviour change **Delivered by:** Trained nurse ("personal coach") **Setting (home/centre):** Residential stay in a centre **Teaching modalities:** A combination of group (5 to 8) and individually oriented intervention formats was used **Involvement of family:** NR **Time of start after event:** NR **Dose:** **Length of session:** 4 weeks, then NR **Frequency/number of sessions:** NR **Total duration:** 12 months **Follow-up further re-inforcement:** yes for 1 year ("regular follow-up contacts between the patient and his/her personal coach for verbal feedback, problem-solving, and replanning discussions when needed (Lisspers 1999)"). **Theoretical basis for intervention:** No **Co-interventions:** Stress management, exercise, smoking habits and dietary advice **Comparator:** One outpatient visit, then referral to family physician. **Co-interventions:** NR
Outcomes	Total mortality Total cardiovascular events, non fatal MI Total revascularisations (both CABG and PCI) Hospitalisations HRQoL: Angina Pectoris Quality of Life Questionnaire (AP-QLQ)
Source of funding	MF Insurance Co, the SPP Insurance Co, and The Swedish Heart and Lung Foundation
Conflicts of interest	NR
Notes	In direct communication with the author he described the program as a "behaviour change program" primarily and he viewed patient education as "secondary and supportive to behaviour change procedures." The following papers produced from the results of the same trial were used to inform the data collected: Hofman-Bang 1999; Lisspers 2005

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	NR

Lisspers 1999 (*Continued*)

Allocation concealment (selection bias)	Unclear risk	NR
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not reported in the paper but from direct communication with the author it was confirmed that those analysing the results were not blinded to the group allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Two patients in the intervention and four in the control group were excluded soon after randomisation at their own request leaving 87 subjects as the final patient population"(Hofman-Bang 1999)
Selective reporting (reporting bias)	Low risk	All stated rehabilitation and secondary prevention endpoints in methods documented in results
Were groups balanced at baseline?	Low risk	Patient characteristics table and statistical comparison included. Apart from beta-blocker usage, groups not different
Intention to treat analysis	Low risk	Intention to treat (ITT) not stated in the test but calculations stated in the results appear to be analysed according to original allocation worked out on an ITT basis
Did both groups receive comparable care?	High risk	As well as education: intervention group received stress management, exercise, smoking habits and dietary advice

Melamed 2014

Methods	**Study design:** Multicentre RCT (13 sites) **Country:** Germany **Dates patients recruited:** February 2010 to September 2011 **When randomised:** Immediately after recruitment and anonymous completion of the baseline questionnaire **Maximum follow up:** 220 days
Participants	**Inclusion criteria:** Patients with CHD and aged 18 to 89 years. Patients with confirmed coronary heart disease in whom an ergometric assessment had been carried out in the 12 weeks preceding the starting date of the study, and who had achieved a level of at least 2 minutes at 75 watts **Exclusion criteria:** NR **N randomised: total:** 407**; intervention:** 202**; comparator:** 205 **Diagnosis (% of pts):** CHD 100% **Age (mean ± SD): total:** NR; **intervention:** 65.7 years**; comparator:** 65.8 years

	Percentage male: total: 79.2%; **intervention:** 79.1%;**comparator:** 79.4% **Ethnicity:** NR
Interventions	**Description of intervention:** The lesson materials consisted of: • A patient brochure • Teaching cards • A curriculum • A poster/wall chart set. The patient brochure was intended for patients' own independent study and for the purpose of repeating the previous module. Patients were able to enter comments and responses to questions, as in a workbook. Additionally, patients were given an exercise diary to enable them to document their daily physical activity **Components:** Education **Delivered by:** Physicians and medical assistants **Setting (home/centre):** Centre **Teaching modalities:** individual **Involvement of family:** NR **Time of start after event:** NR **Dose:** **Length of session:** NR **Frequency/number of sessions:** NR **Total duration:** NR **Follow-up further re-inforcement:** NR **Theoretical basis for intervention:** NR **Co-interventions:** NR **Comparator: P**atients in the control group continued to receive usual care from their primary care physicians/cardiologists **Co-interventions:** NR
Outcomes	HRQoL (MacNew)
Source of funding	NR
Conflicts of interest	"The authors declare that no conflict of interest exists"
Notes	NA

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Random sequence generation was not described
Allocation concealment (selection bias)	Low risk	"The study centre was located at the Bürgerhospital, Frankfurt am Main, and functioned as a central coordinating centre (headed by Ms Kufleitner). She ran-

Melamed 2014 (*Continued*)

		domised patients dynamically and communicated to the study practices whether a patient had been allocated to the intervention group or the control group"
Blinding of outcome assessment (detection bias) All outcomes	High risk	"The study was designed as a randomised controlled and open intervention study"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Intervention group: 21/202 (3.0%) lost to follow-up Control group: 19/205 (3.2%) lost to follow-up
Selective reporting (reporting bias)	Low risk	All outcomes described in the methods section were reported for all time points
Were groups balanced at baseline?	Low risk	Table 1 shows there to be no differences between the groups at baseline
Intention to treat analysis	High risk	"The primary end points were evaluated on the basis of an intention-to-treat analysis according to the LOCF (last observation carried forward) principle (Table 2)." This explanation is contradictory and implies that an intention-to-treat analysis was not actually conducted
Did both groups receive comparable care?	Low risk	No co-interventions are described for either group

Mooney 2014

Methods	**Study design:** Multicentre RCT (5 sites) **Country:** Ireland **Dates patients recruited:** October 2007 to October 2009 **When randomised:** Within 2 to 4 days of hospital admission **Maximum follow up:** 1 year
Participants	**Inclusion criteria:** 1) provisional ACS diagnosis; 2) clinically stable at time of enrolment; 3) access to a telephone; and 4) ability to read, understand, and communicate in English. In all cases, the diagnosis of ACS was based on the European Society of Cardiology Guidelines (2). The criteria included electrocardiograms, biochemical markers, and a physical examination. **Exclusion criteria:** Patients were excluded if they had any condition that prohibited them from understanding the intervention or decision-making process, such as a major or uncorrected hearing loss, a profound learning disability, or any neurological disorder that impaired cognition. Those who lived in an institutional setting and those with

	serious complicating co-morbidities or untreated malignancies were also excluded from the trial **N randomised: total:** 1944*; **intervention:** 972; **comparator:** 972 **Diagnosis (% of pts):** STEMI: **total:** 28.2 ; **intervention:**28.8; **comparator:** 27.6 NSTEMI: **total:** 36.3 ; **intervention:**38.5; **comparator:** 34.1 Unstable angina: **total:** 35.5 ; **intervention:**32.7; **comparator:** 38.4 **Age (mean ± SD): total:** 63.19 ± 11.68 years; **intervention:** 62.55 ± 11.71 years; **comparator:** 63.83 ± 11.62 years **Percentage male: total:** 72.1%; **intervention:** 72.9%;**comparator:** 71.2% **Ethnicity:** NR
Interventions	**Description of intervention:** The intervention was aimed at reducing total pre-hospital delay time. The education was focused on pre-hospital delay and included decision delay, physician delay, and transport delay. The research nurses used preprinted flip charts and prescriptive scripts as educational aids. The educational intervention was individualised to the patient's specific needs and illness experiences, and sought to address the range of potential cognitive and emotional effects that the person with ACS symptoms may have experienced. Positive messages were reinforced and the ways that people tend to respond to symptoms were discussed together with the benefits of prompt reactions to symptoms **Components:** Education **Delivered by:** Research nurse **Setting (home/centre):** Centre **Teaching modalities:** Indiviudal **Involvement of family:** It was agreed that a nominated person would act as a confidant In the presence of symptoms and as a decision-maker, if the patient themselves hesitated to contact the ambulance in the face of unresolved symptoms. If the nominated person was available, s/he was invited to be present during the delivery of the intervention **Time of start after event:** 2 to 4 days **Dose:** **Length of session:** 40 min **Frequency/number of sessions:** 1 **Total duration:** 6 months **Follow-up further re-inforcement:** At the end of the intervention, patients completed an action plan, which they were given to take home as a reminder of what to do if symptoms arose. Patients were telephoned 1 month after the intervention was delivered to reinforce the motivation to adhere to the components of the educational intervention. Six months later, those in the intervention group received a letter by post, which again reinforced the educational intervention and included a written reminder about the main intervention messages **Theoretical basis for intervention:** Leventhal's Self-Regulatory Model of Health and Illness **Co-interventions:** Usual care - which included patient education **Comparator:** Usual care was not completely standardised between the research sites, but broadly comprised pre-discharge patient education with respect to ACS symptoms, medications, modifiable risk factors, and advice about lifestyle adjustments. None of the sites delivered extensive information that focused solely on pre-hospital delay or the factors that influence it **Co-interventions:** NR

Mooney 2014 (*Continued*)

Outcomes	Total mortality Withdrawals
Source of funding	This study was funded by the Health Research Board, Ireland
Conflicts of interest	NR
Notes	*2041 initially randomised, but 94 final diagnosis was not ACS and 3 had no baseline data available

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	A computerised random number generator was used to devise random sequences for the five tertiary hospitals
Allocation concealment (selection bias)	Low risk	The study numbers were allocated sequentially and group assignment was concealed until after baseline data were collected
Blinding of outcome assessment (detection bias) All outcomes	High risk	Blinding of outcome assessors is not described
Incomplete outcome data (attrition bias) All outcomes	Low risk	Intervention: 35/972 (3.6%) lost to follow-up Control: 27/972 (2.8%) lost to follow-up
Selective reporting (reporting bias)	Low risk	All outcomes described in the methods are reported
Were groups balanced at baseline?	High risk	There were some significant differences between characteristics and prognostic factors of the two groups at baseline e.g. age
Intention to treat analysis	Low risk	Although ITT analysis is not described, data from patients lost to follow-up were included in the analyses
Did both groups receive comparable care?	Low risk	Both control and intervention groups received usual in-hospital care

Moreno-Palanco 2011

Methods	**Study design:** Single centre RCT **Country:** Spain **Dates patients recruited:** September 2002 to February 2004 **When randomised:** Before hospital discharge **Maximum follow up:** 3 years
Participants	**Inclusion criteria:** Patients aged 18 to 80 years admitted for ACS (with or without ST segment elevation) or for ischemic stroke **Exclusion criteria:** Refusal or impossibility of participating in the follow-up (patients who moved or had reduced mobility), life expectancy of < 12 months and severe cognitive deterioration **N randomised: total:** 247**; intervention:** 121**; comparator:** 126 **Diagnosis (% of pts):** Ischemic Cardiopathy: **intervention:** 64.5% **; comparator:**66.7% Stroke: **intervention:** 35.5%**; comparator:** 33.3% **Age (mean ± SD): total:** NR; **intervention:** 64.89 ± 11.53 years**; comparator:** 65.60 ± 14.3 years **Percentage male: total:** NR%; **intervention:** 79.3%;**comparator:** 69.8% **Ethnicity:** NR
Interventions	**Description of intervention:** The patients received health education informing them of their disease and the importance of carrying out correct treatment. Subsequently, visits were programmed at 2, 5, 12, 24, and 36 months after the acute episode, with the possibility of more visits if considered appropriate. Patients could consult with other specialists related to their cardiovascular disease. Each visit consisted of a nursing intervention (health education, lifestyle modifications, evaluation of adherence to treatment) and a medical assessment (clinical evaluation and modification of treatment, if appropriate) **Components:** Education **Delivered by:** Trained nurse **Setting (home/centre):** Centre **Teaching modalities:** Individual **Involvement of family:** NR **Time of start after event:** NR **Dose:** **Length of session:** NR **Frequency/number of sessions:** At least 5 sessions **Total duration:** 3 years **Follow-up further re-inforcement:** NR **Theoretical basis for intervention:** NR **Co-interventions:** NR **Comparator:** Usual follow-up in cardiology or neurology and/or primary care consulting offices **Co-interventions:** NR
Outcomes	Total mortality Cardiovascular mortality Non-cardiovascular mortality Total cardiovascular events Fatal and/or non-fatal MI Other fatal and/or non-fatal cardiovascular events

Source of funding	NR
Conflicts of interest	"None declared"
Notes	NA

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"randomisation by blocks…assigned each patient to either the intervention group or the control group using a computer generated list"
Allocation concealment (selection bias)	Low risk	"…using a computer generated list, with a different person in charge of this task than of the previous tasks"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"The evaluation was carried out by a non-blinded member of the research team"
Incomplete outcome data (attrition bias) All outcomes	High risk	Intervention: 3/121 (2.5%) lost to follow-up Control: 5/126 (4.0%) lost to follow-up
Selective reporting (reporting bias)	Low risk	All outcomes described in methods are reported
Were groups balanced at baseline?	Low risk	There were no significant differences between characteristics or prognostic factors
Intention to treat analysis	Low risk	"Data analysis was carried out based on intention to treat"
Did both groups receive comparable care?	Low risk	Neither group received any co-interventions

P.RE.COR Group 1991

Methods	**Study design:** Multicentre RCT (4 sites); 3 groups **Country:** France **Dates patients recruited:** Feb 1981 to May 1984 **When randomised:** 30 to 60 days post MI **Maximum follow up:** 24 months
Participants	**Inclusion criteria:** MI < 65 years **Exclusion criteria:** Contraindicaton to exercise: recent stroke, disability lower limbs, uncontrolled heart failure, severe rhythm disturbances, systolic blood pressure > 250 mm Hg, severe angina pectoris, severe hypotension, chest pain or low heart rate on exercise **Recruitment from:** Coronary Care Unit of the four participating hospitals **N randomised: total:** 182**; intervention:** 60**; comparator I** "Counselling programme"**:** 61; **comparator II** "Usual care"**:** 61 **Diagnosis (% of pts):** Post MI: 100% **Age (mean): total:** 50.3 years; **intervention:** 51 years**; comparator I:** 51 years; **comparator II:** 49 years **Percentage male: total:** 100%; **intervention:** 100%;**comparator:** 100% **Ethnicity:** NR
Interventions	**Description of intervention:** Recommendations were given about control of cardiovascular risk factors and physical standardised exercise. Patients were also seen privately by the cardiologist in charge of the programme for a full medical examination and personal adjustment of the recommendations **Components:** Education **Delivered by:** Cardiologist **Setting (home/centre):** Centre **Teaching modalities:** One group session, plus individual session with Cardiologist **Involvement of family:** Spouse/partner encouraged to attend **Time of start after event:** NR **Dose:** **Length of session:** NR **Frequency/number of sessions:** One **Total duration:** NR **Follow-up further re-inforcement:** No **Theoretical basis for intervention:** No **Co-interventions:** There was no restriction or recommendation in the three groups for any other concomitant therapies **Comparator:** Patients randomised to a counselling programme attended a group session with a cardiologist, a psychiatrist, a nutritionist and a physiotherapist whenever possible Patients in the usual care group were just referred to their usual private practitioner and/or cardiologist **Co-interventions:** There was no restriction or recommendation in the three groups for any other concomitant therapies
Outcomes	Mortality Cardiovascular events

P.RE.COR Group 1991 (*Continued*)

Source of funding	Institut National de la Santé et de la Recherche Médicale, by the Hospices Civils de Lyon and by the Association pour la Promotion et la Réalisation d'Essais Thérapeutiques
Conflicts of interest	NR
Notes	NA

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	NR
Allocation concealment (selection bias)	Unclear risk	NR
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	NR
Incomplete outcome data (attrition bias) All outcomes	Low risk	Reasons for exclusions pre-randomisation given. "Exclusion of women and men above the age of 65 alone contributed to almost 60% of all reasons for non-eligibility...the reasons for non-inclusion in the other patients were either inability to perform the exercise test or major ECG abnormalities." "No patient was lost to follow-up" but number actually completing interventions not reported. Results for all those randomised, reported for non-fatal events and mortality outcomes
Selective reporting (reporting bias)	Low risk	All outcomes listed in methods reported in results
Were groups balanced at baseline?	Low risk	"No statistically significant differences were observed among the treatment groups for any of the tested variable"
Intention to treat analysis	Low risk	*"The analysis followed the intention-to-treat principle; patients were counted in the groups in which they were allocated"*
Did both groups receive comparable care?	Low risk	Intervention and control group received identical care other than the intervention stated

Park 2013

Methods	**Study design:** Single centre RCT **Country:** South Korea **Dates patients recruited:** March 2010 to November 2010 **When randomised:** After baseline measures **Maximum follow up:** 6 months
Participants	**Inclusion criteria:** (i) Patients from 18 to 70 years of age with first hospitalisation diagnosed with either angina pectoris or MI and who had scheduled PCI; (ii) Willing to participate in this study; and (ii) Able to speak, read and write Korean. **Exclusion criteria:** (i) Planning for surgical treatment; (ii) Previous revascularisation; (iii) Aged < 18 years or > 70 years; (iv) diagnosis of psychosis or currently on antipsychotic medications; and (v) diagnosed with a terminal illness **N randomised: total:** 63**; intervention:** 31**; comparator:** 32 **Diagnosis (% of pts):** Angina:**intervention:** 20.0 **comparator:** 3228.6 Myocardial:**intervention:** infarction 80.0 **comparator:** 3271.4 **Age (mean ± SD): total:** NR; **intervention:** 57.89 ± 7.96 years**; comparator:** 58.27 ± 8.56**years** **Percentage male: total:** NR; **intervention:** 82.1%;**comparator:** 83.2% **Ethnicity:** NR
Interventions	**Description of intervention:** The 12-week psycho-educational intervention consisted of individual face-to-face education using a tailored resource package and telephone - delivered health coaching. It began with a risk factor assessment, focusing on lifestyle changes related to the risk factors and some biological risk indicators for CAD and was performed using individual face-to-face education. Next, the patients made guided choices about which risk factors they wanted to lower and participated in goal setting informed by current national targets for the chosen risk factors. They selected the management options they would use to lower the risks and were provided with a tailored resource package that was developed in consultation with clinical experts In addition, patients in the intervention group received up to six telephone delivered health coaching (every other week) throughout the 12-week period. This biweekly telephone delivered health coaching helped patients to develop management plans that included giving advice and information for specific concerns or problems, reinforced education, and for counselling/support **Components:** Education **Delivered by:** NR **Setting (home/centre):** Centre then home (telephone call) **Teaching modalities:** Individual **Involvement of family:** NR **Time of start after event:** NR **Dose:** Initial face-to face meeting plus telephone-delivered health coaching: **Length of session:** 10 to 40 minutes **Frequency/number of sessions:** Every other week (6 sessions) **Total duration:** 12 weeks **Follow-up further re-inforcement:** NR **Theoretical basis for intervention:** NR **Co-interventions:** NR **Comparator:** Standard care from the medical team. Patients were provided with a short

	booklet on general guidelines related to CAD and were instructed to contact their medical team to continue with follow-up care **Co-interventions:** NR
Outcomes	Total cardiovascular events Withdrawals
Source of funding	Basic Science Research Program through the National Research Foundation of Korea (NRF) funded by the Ministry of Education, Science and Technology
Conflicts of interest	NR
Notes	NA

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Random assignment was based on the last digit of the patient's identification number, with even numbers assigned to the intervention group and odd numbers assigned to the control group."
Allocation concealment (selection bias)	High risk	Allocation concealment not described
Blinding of outcome assessment (detection bias) All outcomes	High risk	Blinding of outcome assessors is not described
Incomplete outcome data (attrition bias) All outcomes	Low risk	Intervention: 3/31 (9.7%) lost to follow-up Control: 2/32 (6.3%) lost to follow-up
Selective reporting (reporting bias)	Low risk	All outcomes described in the methods are reported
Were groups balanced at baseline?	Low risk	"There were no significant differences in the sociodemographic and disease/treatment-related characteristics between the two groups."
Intention to treat analysis	High risk	ITT analysis is not described and data from patients lost to follow-up were not included in the analyses
Did both groups receive comparable care?	High risk	Intervention includes psychological support and counselling

Peikes 2009

Methods	**Study design:** Multicentre RCT (15 sites) **Country:** USA **Dates patients recruited:** April 2002 and June 2005 **When randomised:** NR **Maximum follow up:** At least 1 year. Mean follow-up 51 months.
Participants	**Inclusion and exclusion criteria:** "Each program was allowed to define within broad boundaries its own target population and exclusion criteria, and designed its intervention accordingly." 10/15 sites required a hospital admission within the previous year, 4/15 sites excluded < 65 years old and 14/15 excluded "terminal illness and conditions that affected their ability to learn self management" **Recruitment from:** Eligible-fee for service Medicare patients from 15 care co-ordination programs **N randomised: total:** 18,402**; intervention:** 9,427**; comparator:** 8,975 **Diagnosis (% of pts):** CHD: 61% Congestive heart failure: 48% **Age (mean ± SD): total:** NR; **intervention:** NR**; comparator:** NR **Percentage male: total:** 45%; **intervention:** NR;**comparator:** NR **Ethnicity:** 85% white
Interventions	**Description of intervention:** The care coordination interventions of the 15 programs differed widely. All of the programs assigned patients to a care coordinator.Nurses provided patient education and monitoring. All but one of the programs educated patients to improve adherence to medication, diet, exercise, and self-care regimens,mostly through the nurses conveying factual information. Seven programs also used behaviour change models such as the transtheoretical approach or techniques such as motivational interviewing **Components:** Education and behaviour change **Delivered by:** Care co-ordinator. Licensed or registered nurses (4 programs required a BSc level qualification in nursing studies) **Setting (home/centre):** NR **Teaching modalities:** All programs contacted patients primarily by telephone; however, 4 programs contacted patients in person nearly once a month as well **Involvement of family:** NR **Time of start after event:** NR **Dose:** **Length of session:** NR **Frequency/number of sessions:** 11 programs: 1 to 2.5 times/month: 3 programs 4 to 8 times/month. Other programs did not record contact frequency **Total duration:** On average 30 months eligibility (range 18 to 31 months) **Follow-up further re-inforcement:** NR **Theoretical basis for intervention:** NR **Co-interventions:** Seven programs also used behaviour change models such as the transtheoretical approach or techniques such as motivational interviewing **Comparator:** Not described **Co-interventions:** NR

Outcomes	Hospitalisations HRQoL Cost analysis - monthly Medicare expenditure
Source of funding	Centers for Medicare & Medicaid Services. There were no industry sponsors of this study. The writing of the manuscript was funded solely by Mathematica Policy Research Inc
Conflicts of interest	The authors are all salaried employees of Mathematica Policy Research Inc and receive no compensation from any other source. They do not own stock in any of the programs being evaluated or stand to profit in any way, directly or indirectly, from particular findings in this article
Notes	The following paper produced from the results of the same trial were used to inform the data collected: Brown 2008

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomly generated concealed 4-digit "strings"
Allocation concealment (selection bias)	Low risk	Randomised assignment was returned via the trial web site
Blinding of outcome assessment (detection bias) All outcomes	High risk	"Because of the nature of the intervention, no individuals were blinded to which group participants were randomised." Peikes 2009
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"Observations are weighted by the number of months in the follow-up period that the same member meets eligibility requirements." Peikes 2009. A full breakdown of periods that patients were eligible is not given
Selective reporting (reporting bias)	Low risk	All outcomes stated in the methods are reported in the results
Were groups balanced at baseline?	Low risk	"Across all of the 15 programs and the baseline characteristics the treatment and control groups differed significantly on only 11 of the 255 comparisons at the p<0.05 level, less than the expected number of statistical significant differences that would be observed by chance." Peikes 2009

Peikes 2009 (*Continued*)

Intention to treat analysis	Low risk	"Effects were calculated using...an intention to treat design." Peikes 2009
Did both groups receive comparable care?	High risk	"7 of the programs used behaviour change models. 14 programs attempted to improve communication between patients and physicians." Peikes 2009 Education was not the only intervention that the treatment groups received

Pogosova 2008

Methods	**Study design:** Single centre RCT **Country:** Russia **Dates patients recruited:** NR (total study period: March 2004 to January 2006) **When randomised:** NR **Maximum follow up:** 12 months
Participants	**Inclusion criteria:** Diagnosis of CHD, stable angina, age < 65 years **Exclusion criteria:** ACS and acute cerebrovascular disorders in 6 months before selection; patients with severe somatic disorders (life-threatening arrhythmia, heart failure (3 to 4 functional class), kidney or liver failure; decompensated diabetes, severe bronchial asthma), psychiatric disorders and alcoholic, narcotic and prescription drug addictions **Recruitment from:** Ambulatory patients of the Moscow polyclinic **N randomised: total:** 100**; intervention:** 50**; comparator:** 50 **Diagnosis (% of pts):** Angina: 100% Post MI: **intervention**: 52%; **comparator**: 48% Post CABG: **intervention:** 14%; **comparator**:8% Post PCI: **intervention:** 18%; **comparator**: 14% **Age (mean ± SD): total:** 59.9 ± 0.4 years; **intervention:** 59.3 ± 0.69 years**; comparator:** 60.5 ± 0.48 years **Percentage male: total:** 59%; **intervention:** 60%;**comparator:** 58% **Ethnicity:** NR
Interventions	**Description of intervention:** A course at the "Health school for CHD patients"; Structured programme of 6 sessions (90 min each, twice a week), during which 1 or 2 risk factors were discussed. Evaluation of knowledge about the disease and risk factors after the course **Components:** Education **Delivered by:** Outpatient doctors **Setting (home/centre):** Centre **Teaching modalities:** Group **Involvement of family:** NR **Time of start after event:** NR **Dose:** **Length of session:** 90 minutes **Frequency/number of sessions:** twice a week (6 sessions total)

	Total duration: 3 weeks **Follow-up further re-inforcement:** NR **Theoretical basis for intervention:** Organisation of Health Schools for CHD patients in practical health-care setting. Organisational-methodical letter. Appendix 2. M 2003 **Co-interventions:** NR **Comparator:** Usual care (for all patients) consisted of three visits during a 12 months follow-up. First visit - evaluating inclusion criteria, giving informed consent, randomisation, evaluation of knowledge about the disorder and risk factors; clinical examination; blood test for lipids and glucose; psychological survey. Second and third visits - 6 and 12 months after the start of the study; consisted of clinical examination (blood test for lipids and glucose), evaluation of knowledge and psychological survey **Co-interventions:** NR
Outcomes	HRQoL: SF36
Source of funding	NR
Conflicts of interest	NR
Notes	NA

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	NR
Allocation concealment (selection bias)	Unclear risk	NR
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	NR
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Likely, description of the results in text indicates missing data but no breakdown given
Selective reporting (reporting bias)	Low risk	All outcomes are accounted for in the results in either table, graphical or text format
Were groups balanced at baseline?	Low risk	Groups at baseline were comparable
Intention to treat analysis	Unclear risk	NR
Did both groups receive comparable care?	Low risk	Control group received standard care only

Southard 2003

Methods	**Study design:** Multicentre RCT **Country:** USA **Dates patients recruited:** NR (10 month period) **When randomised:** NR **Maximum follow up:** 6 months
Participants	**Inclusion criteria:** Diagnosis of CHD or CHF or both. Approval of either primary care physician or cardiologist. Need access to the Internet **Exclusion criteria:** NR **Recruitment from:** 46 outpatient facilities throughout SW Virginia or through newspaper adverts **N randomised: total:** 104**; intervention:** 53**; comparator:** 51 **Diagnosis (% of pts):** CHD, or congestive heart failure or both Breakdown not reported. **Age (mean ± SD): total:** 61.8 ± 10.6 years; **intervention:** 62.8 ± 10.6 years**; comparator:** 62.3 ± 10.6 years **Percentage male: total:** 75%; **intervention:** 67%;**comparator:** 72 % **Ethnicity:** 97% white
Interventions	**Description of intervention:** Log in to the site at least once a week for 30 min, communicating with a case manager through a secure form of e-mail, completing education modules assigned by the case manager, and entering data into progress graphs. Participants had the opportunity to use an on-line discussion group. There were material incentives for active participation. Also dietary input **Components:** Education **Delivered by:** "Case Managers" and dieticians **Setting (home/centre):** Home **Teaching modalities:** Interactive, multiple choice, self tests followed by feedback **Involvement of family:** NR **Time of start after event:** NA **Dose:** ***Length of session:*** at least 30 min **Frequency/number of sessions:** one/week **Total duration:** 6 months **Follow-up further re-inforcement:** No **Theoretical basis for intervention:** NR **Co-interventions:** NR **Comparator:** Usual care (details not explicitly stated) **Co-interventions:** NR
Outcomes	Total cardiovascular Events (fatal/nonfatal MI and other fatal/nonfatal cardiovascular event) Total revascularisations (PCI) Hospitalisations HRQoL - Dartmouth COOP QoL Cost analysis
Source of funding	The Agency for Healthcare Research and Quality

Southard 2003 (*Continued*)

Conflicts of interest	NR	
Notes	NB. Included heart failure not just CHD patients; percentage with just heart failure not clear; the breakdown table shows "multiple diagnoses" Included a proportion of patients who had previously received cardiac rehabilitation	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Randomly assigned to SI or UC on the basis of a computer-generated random number." "study population was stratified on the basis of minority status, participation in cardiac rehabilitation, and acute status (time since event)"
Allocation concealment (selection bias)	Unclear risk	NR
Blinding of outcome assessment (detection bias) All outcomes	High risk	Case managers collected number of outcomes (height, weight, blood pressure) at follow up and were not blind to intervention or control
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Of the 104 subjects randomised to the study, 6-month follow-up data was obtained on 100. Four subjects were lost to follow up evaluation." Details of withdrawals/loss to follow up reported
Selective reporting (reporting bias)	High risk	Dartmouth COOP QoL taken at entry and exit. Results reported on entry but not at exit
Were groups balanced at baseline?	Low risk	Table of demographics and baseline outcome values presented and baseline statistical analysis did not demonstrate any differences
Intention to treat analysis	Low risk	Although not explicitly stated, there groups appear to have been analysed according to initial random allocation
Did both groups receive comparable care?	Unclear risk	Not clear if intervention group received same usual care as control arm

Tingström 2005

Methods	**Study design:** Multicentre RCT (2 sites) **Country:** Sweden **Dates patients recruited:** NR **When randomised:** NR **Maximum follow up:** 12 months
Participants	**Inclusion criteria:** Recent CAD; MI and/or PCI and/or CABG **Exclusion criteria:** Planned CABG; senility; psychiatric medication; expected poor prognosis within a year; deficient in Swedish; participation in other studies. **Recruitment from:** consecutive patients from 2 participating hospitals **N randomised: total:** 207**; intervention:** 104**; comparator:** 103 **Diagnosis (% of pts):** Post MI: 40.5% MI and/or post CABG: 22% MI and/or post PCI: 37% **Age (mean ± SD): total:** 59 ± 7 years; **intervention:** 59 ± 7 years**; comparator:** 59 ± 7 years **Percentage male: total:** 74%; **intervention:** 72%;**comparator:** 76% **Ethnicity:** NR
Interventions	**Description of intervention:** The PBL programme was run within CR at the two participating hospitals. The first meeting focused on information about the pedagogic model of learning, the content of the programme, and the role of the tutor. Real-life situations or scenarios were presented, consisting of pictures, press cuttings, or short texts about exercise, food, drugs, smoking, and cholesterol. They were produced in accordance with the planned curriculum for the programme, which included manifestations of CAD and its symptoms, psychological reactions to the disease, psychosocial factors, stress, smoking, metabolic factors, food and alcohol, physical exercise, sex life, revascularisation procedures, and drug treatment. During the second group meeting, the participants were presented with a scenario chosen to illustrate the whole life situation for patients with CAD. They then decided which particular aspects they would choose to focus on, and a priority list of problem areas was made. A structured problem solving process was used to facilitate the work in tutorial groups and to stimulate self-directed learning. Every group member was given a diary in which to write down goals for learning and for own lifestyle changes **Components:** Education **Delivered by:** Tutor - member of rehabilitation team, trained to take the role of the facilitator **Setting (home/centre):** Centre **Teaching modalities:** Groups of 6 to 8 people **Involvement of family:** NR **Time of start after event:** NR **Dose:** **Length of session:** 1.5 hours **Frequency/number of sessions:** 13 group sessions (weekly for the first month, every other week for the next month and the spread over the year) **Total duration:** 1 year **Follow-up further re-inforcement:** NR **Theoretical basis for intervention:** Schmidt seven step model of problem solving

	Co-interventions: Participants were offered standard treatment by the rehabilitation team, including visits to a nurse and physician. All patients were also offered the possibility of taking part in physical exercise groups, smoking cessation groups, and individual counselling by a dietician **Comparator:** Standard treatment by the rehabilitation team, including visits to a nurse and physician **Co-interventions:** All patients were also offered the possibility of taking part in physical exercise groups, smoking cessation groups and individual counselling by a dietician
Outcomes	HRQoL - Ladder of Life, Self-Rated Health, SF-36, Cardiac Health Profile Withdrawal from intervention group
Source of funding	Vardal Foundation, the Swedish Heart- and Lung Association and the Swedish Heart- and Lung Foundation
Conflicts of interest	NR
Notes	High attendance rate to the educational sessions. Mean 9.4 (median 11) out of 13 sessions

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Not reported in the study itself but from communication with the author it was confirmed that sealed envelopes were randomly organised by a person outside of the research team
Allocation concealment (selection bias)	Low risk	Not reported in the study. However, from communication with the author a sealed envelope method was used
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not reported in the study. Confirmed by communication with author
Incomplete outcome data (attrition bias) All outcomes	Low risk	QUORUM trial flow diagram reported with exclusions and attrition documented and reasons given
Selective reporting (reporting bias)	Low risk	All stated outcomes in methods are reported in results at pre and post tests. Although the self rated health score was not reported in detail
Were groups balanced at baseline?	Low risk	Table of baseline characteristics showed no statistically differences

Tingström 2005 (*Continued*)

Intention to treat analysis	Low risk	Confirmed by communication with the author. "For all analyses intention to treat was used."
Did both groups receive comparable care?	Low risk	"both groups were offered standard treatment by the rehabilitation team..."

Abbreviations:
ACS: acute coronary syndrome; AMI: acute myocardial infarction; CABG: coronary artery bypass graft; CAD: coronary artery disease; CHD: coronary heart disease; CR: cardiac rehabilitation; HRQoL: health related quality of life; ITT: intention to treat; MI: myocardial infarction; NR: not reported; PCI: percutaneous coronary intervention; pts: participants; RCT: randomised controlled trial; SD: standard deviation; SF-36: Short Form 36; STEMI: ST segment elevation myocardial infarction; USA: United States of America

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Abbaszadeh 2011	No outcomes of interest
Abbaszadeh 2012	No outcomes of interest
Ades 2001	Identifed from Lie 2009. Review not a RCT
Allen 2010	Systematic Review: 21 references identified and reviewed as being of potential interest to this review
Allison 2000	Education not primary aim of intervention. (Risk Factor intervention clinic)
Ammenwerth 2015	Follow-up less than 6 months
Arthur 2000	Performance bias, intervention included exercise as well as education
Bagheri 2007	Education not primary aim of intervention. (Psychological Counselling)
Balasch 2011	An observational retrospective study
Barley 2014	Education not primary aim of intervention
Barnason 1995	*"quasi-experimental"* investigating patient satisfaction with teaching.
Barnason 2006	Performance bias: education only part of the intervention.
Barnason 2009	Education not primary aim of intervention: symptom management intervention (pain management / incremental physical exercise.)

(*Continued*)

Barnason 2009a	Performance bias: education only part of the intervention.
Barnes 2012	No outcomes of interest
Bell 1998	Identified from Clark 2007. Not RCT.
Benson 2000	A review of a meta-analysis Dusseldorp 1999
Beranova 2007	Systematic Review: 2 references identified and reviewed as being of potential interest to this review
Bethell 1990	Identified from Clark 2005. Education not primary aim of intervention (Exercise based intervention)
Bettencourt 2005	Not education: exercise intervention.
Bitzer 2002	Not a RCT.
Bjørnnes 2015	No outcomes of interest
Boulay 2004	Performance bias, intervention included exercise as well as education. Not a RCT compared with historical controls
Brand 1998	Performance bias, intervention included exercise as well as education
Brügemann 2007	Education not primary aim of intervention. Psychological - *"Rational Emotive behavioural therapy".*
Campbell 1998	Education not primary aim of intervention (nurse intervention clinic)
Campbell 1998a	Education not primary aim of intervention (nurse intervention clinic)
Cannon 2002	Review of implementation of Acute Coronary Syndrome patient pathway. Not an intervention
Carrington 2013	Education not primary aim of intervention
Cebeci 2008	No relevant outcomes - self care questionnaires.
Chan 2005	Identified from Eshah 2009. Not RCT: Prospective pre-test / post-test design.
Chan 2012	Education not primary aim of intervention
Chen 2005	No specified follow-up period.
Cho 2010	Follow-up was "two weeks after discharge. "
Cingözbay 2011	Comment paper
Clark 2005	Systematic Review: 45 references identified and reviewed as being of potential interest to this review

(*Continued*)

Clark 2007	Systematic Review: 35 references identified and reviewed as being of potential interest to this review
Cobb 2006	Systematic Review: 3 references identified and reviewed as being of potential interest to this review
Coburn 2012	Education not primary aim of intervention
Costa e Silva 2008	Education not primary aim of intervention - multidisciplinary interventional clinic
Coull 2004	Entrance into study after cardiac rehabilitation.
Crumlish 2011	Population doesn't have CHD
Cundey 1995	Identifed from Hanssen 2007. Review not an RCT
Dankner 2011	Not an RCT design
DeBusk 1994	Education not primary aim of intervention. Nurse led intervention
Delaney 2008	Education not primary aim of intervention - a nurse led intervention clinic
Devi 2014	Education not primary aim of intervention
Divison 2014	Comment article
Dusseldorp 1999	Systematic Review: 12 references identified and reviewed as being of potential interest to this review
Dusseldorp 2000	Commentary on a meta-analysis: Dusseldorp 1999
Eckman 2012	Comparator group received education
Engblom 1992	Performance bias: Intervention multifactorial involves exercise and psychological therapy
Engblom 1994	Performance bias: Intervention multifactorial involves exercise and psychological therapy
Engblom 1996	Performance bias: Intervention multifactorial involves exercise and psychological therapy
Engblom 1997	Performance bias: Intervention multifactorial involves exercise and psychological therapy
Enzenhofer 2004	Identified from Beranova 2007. Not relevant outcomes.
Eshah 2009	Systematic Review: 8 references identified and reviewed as being of potential interest to this review
Eshah 2010	Population doesn't have CHD
Eshah 2013	A non-equivalent control group pretest-post-test design was used
Eshah 2014	A non-equivalent control group pretest-post-test design was used

(*Continued*)

Espinosa Caliani 2004	Education not primary aim of intervention- Performance bias
Fang 2015	No outcomes of interest
Fattirolli 1998	Education not primary aim of intervention: Exercise intervention
Fernandez 2009	Intervention cognitive behavioural therapy compared with standard cardiac rehabilitation (including education)
Frasure-Smith 1997	Education not primary aim of intervention: Individualised psychological intervention
Fredericks 2009	Individualised educational intervention in CABG patients: Study designed to investigate the time of delivery of education - both groups received the same intervention
Fredericks 2009a	Systematic Review: 7 references identified and reviewed as being of potential interest to this review
Fredericks 2013	Comparator group received education
Frederix 2015	Education not primary aim of intervention
Froelicher 1994	Not relevant outcomes (patients recruited between 1977 and 79)
Furze 2012	Education not primary aim of intervention
Gao 2007	Not education, exercise is the primary focus post CABG.
Ghali 2004	Commentary: paper excluded education not primary intervention
Goodman 2008	Follow-up period only 3 months post discharge from CABG.
Han 2011	Education not primary aim of intervention
Harbman 2006	Commentary on meta-analysis Clark, A.M., et al., Meta-analysis: Secondary prevention programs for patients with coronary artery. Annals of Internal Medicine, 2005. 143(9): p. 659-672+I87
Haskell 1994	Identified from Clark 2007. Education not primary aim of intervention
Hawkes 2009	ID from 2011 update: No outcomes of interest
Hazavei 2012	Follow up less than 6 months and no outcomes of interest
He 2012	Education not primary aim of intervention
Hedback 1993	Education not primary aim of intervention - Performance bias
Hedback 2001	Education not primary aim of intervention - Performance bias

(*Continued*)

Heidarnia 2005	Not RCT *"experimental design"*
Heilmann 2014	Follow-up only 5 days after intervention
Hobbs 2002	Editorial referring to Shuldham 2002, Pre-CABG education. No relevant outcomes investigated.
Hoseini 2013	Follow-up only 6 weeks
Huang 2014	No outcomes of interest
Huber 2016	No outcomes of interest
Jackson 2009	Systematic Review: 0 references identified
Jamshidi 2013	Comparator group received education
Janz 1999	Identified from Clark 2009. No relevant outcomes.
Jenny 2001	Identifed from Beranova 2007. Outcomes; Effectiveness of education package in promoting learning only
Johansen 2003	Not education, psycho-social intervention, post MI.
Kamal 2014	No outcomes of interest
Khunti 2007	Education not primary aim of intervention. Nurse led clinic.
Klainin-Yobas 2015	Education not primary aim of intervention
Koertge 2003	Identified from Eshah 2009. Education not primary aim of intervention (diet and stress management and social support)
La Sala 2015	Education not primary aim of intervention
Leemrijse 2012	Education not primary aim of intervention
Levine 2011	No outcomes of interest
Lindsay 2009	Education not primary aim of intervention: computer support group - comparison of moderated and unmoderated access
Luisi 2015	No outcomes of interest
Ma 2012	Comparator group received education
Mayou 2002	Education not primary aim of intervention
McGillion 2004	Systematic Review: 0 references identified

(*Continued*)

McGillion 2006	ID from 2011 update: Follow-up only 3 months
McGillion 2008	Education not primary aim of intervention: Psychological intervention - cognitive behavioural therapy
McGillion 2008a	Education not primary aim of intervention-Psychological intervention
Meisinger 2013	Education not primary aim of intervention
Meng 2014	Quasi-experimental, sequential cohort design study
Mirkamali 2014	No outcomes of interest
Mohammadpour 2015	Intervention included counseling and no outcomes of interest and
Mohammady 2010	Follow-up only 3 months and no outcomes of interest
Moore 2001	Identified from Fredericks 2009. Education not primary aim of intervention. Symptom management program using audiotapes
Mosca 2010	No outcomes of interest
Moser 2012	Intervention included counseling and no outcomes of interest and
Mullen 1992	Duplicate of Dolan 1992; Systematic Review: 0 references identified (all pre1990)
Murchie 2003	Education not primary aim of intervention: secondary prevention clinic
Murchie 2004	Education not primary aim of intervention: secondary prevention clinic
Muñiz 2010	Education not primary aim of intervention
NCT00683813	ID from 2011 update: Education not primary aim of intervention
Nelson 2013	Education not primary aim of intervention
Nematian 2015	Follow-up less than 6 months
Neubeck 2009	Systematic Review: 11 references identified and reviewed as being of potential interest to this review
Niebauer 1997	Identified from Clark 2007. Education not primary aim of intervention (exercise and low fat diet)
Nisbeth 2000	Education not primary aim of intervention: psychological intervention
Nolan 2011	No outcomes of interest
Nordmann 2001	Education not primary aim of intervention: case management - not relevant outcomes (only risk factor modification)

(*Continued*)

O'Neil 2011	Education not primary aim of intervention; no outcomes of interest (protocol)
O'Neil 2014	Education not primary aim of intervention; no outcomes of interest
O'Neil 2014a	No outcomes of interest
Oldenburg 1995	Education not primary aim of intervention: psychological intervention
Oranta 2012	Education not primary aim of intervention
Ornish 1990	Identified from Clark 2007. Education not primary aim of intervention
Ornish 1998	Education not primary aim of intervention: lifestyle regime
Paez 2006	Education not primary aim of intervention: nurse managed cholesterol control program
Palacio 2015	Education not primary aim of intervention
Parry 2009	No relevant outcomes
Peterson 2012	Education not primary aim of intervention
Raftery 2005	Education not primary aim of intervention
Redaelli 2010	Education not primary aim of intervention
Redfern 2009	Non-standard RCT design with non-randomised control group.
Robertson 2003	Not RCT. *"True experimental post-test only, control group design, including the process of randomisation."*
Rubenfire 2008	Commentary on a Systematic Review, subsequently reviewed and demonstrated: 9 references identified and reviewed as being of potential interest to this review
Saffi 2014	Education not primary aim of intervention
Saki 2014	Follow up less than 6 months
Schneider 2012	Transcendental Meditation Intervention vs health education (control)
Schwalm 2015	Education not primary aim of intervention
Seekatz 2013	Comparator group received education
Shahamfar 2010	No outcomes of interest
Sherrard 2000	Education not primary aim of intervention, combined with psychological counselling and no relevant outcomes

(*Continued*)

Shui 2014	Follow-up only 30 days after leaving hospital.
Shuldham 2001	Systematic Review: 0 references identified
Shuldham 2002	pre-CABG education. No relevant outcomes investigated.
Sinclair 2005	Follow-up only 100 days.
Stewart 2012	Education not primary aim of intervention
Stewart 2013	Education not primary aim of intervention
Stewart 2014	Education not primary aim of intervention
Thompson 2000	Identified from Hanssen 2007. Review not an RCT
Thompson 2002	Identified from Hanssen 2007. Review not an RCT
Tranmer 2004	Education not primary aim of intervention, telephone nurse management
Turner 2008	Cost analysis of Khunti 2007; Education not primary aim of intervention
Uysal 2012	Follow-up only 3 months
Uysal 2015	Not an RCT; follow-up only 3 months post-discharge
Vale 2003	Education not primary aim of intervention: Program is a risk factor targeted prompting of treatment
Van Elderen 1994	No relevant outcomes.
Van Elderen 2001	Not RCT -*" quasi-experimental pre-test / post test control group design."*
Vida 2011	Follow-up only 8 weeks
Volpe 2012	Population doesn't have CHD
Vonder Muhll 2002	Identified from Eshah 2009. Not RCT: Retrospective Study
Wallner 1999	Dietary intervention, Education not primary aim of intervention
Wang 2010	Education not primary aim of intervention
Wang 2012	Education not primary aim of intervention
Wang 2015	No outcomes of interest
Weibel 2016	No outcomes of interest

(*Continued*)

Williams 2009	Systematic Review: 0 references identified.
Williamson 2008	Listed under "Studies awaiting assessment" in 2011 update: Unable to find full publication
Wolkanin 2010	Follow-up only 3 months and no outcomes of interest
Wolkanin-Bartnik 2011	No outcomes of interest
Yavarikia 2011	No outcomes of interest
Yildiz 2014	Comparator group received education
Zalesskaya 2005	No relevant outcomes.
Zhao 2009	Education not primary aim of intervention-Performance bias
Zhao 2015	No outcomes of interest
Zhou 2014	Comparator group received education
Zutz 2007	Identified from Neubeck 2009. No relevant outcome measures

Characteristics of studies awaiting assessment *[ordered by study ID]*

Gao 2011

Methods	Not available
Participants	Not available
Interventions	Not available
Outcomes	Not available
Notes	Published in IIOAB but cannot access any of this journal's web pages

Licina 2010

Methods	RCT
Participants	355 patients (mean age 59 ± 9 years; 258 male) consecutively admitted for control exercise stress test after PCI
Interventions	Education on lifestyle modification regarding dietary habits, physical activity, stress management, smoking status, lipid status, fasting blood glucose, blood pressure and adherence to treatment
Outcomes	Primary outcome was a change in risk factor management

Licina 2010 (*Continued*)

Notes	Unable to find full text or trace authors

Soliman 2013

Methods	RCT
Participants	1850 post MI patients
Interventions	MI educational program: Patients participated in a 30 min weekly education session for eight weeks. Follow up telephone calls after another 4 weeks
Outcomes	Smoking cessation; overweight; diet modifications; physical activity
Notes	Unable to find full text or trace authors

Vona 2009

Methods	RCT; 3 groups: usual care (G1, 214 patients); phone follow-up group (G2, 193 patients), intensive long-term intervention group (G3, 204 patients)
Participants	611 patients (57 ± 9 year), following an acute coronary event
Interventions	The G2 patients were called every month by a nurse to reinforce adherence to medical treatment and physical activity recommended and to check progress regarding lifestyle and other risk factors changes; the G3 patients underwent, every 3 months, 2 hours of a risk factors - education counselling session managed by nurse
Outcomes	Total and cardiovascular mortality; MI; hospitalisations; LDL cholesterol; adherence to medical treatment; adherence to physical activity; blood pressure
Notes	Unable to find full text or trace authors

Xiaolin 2012

Methods	Not available
Participants	Not available
Interventions	Not available
Outcomes	Not available
Notes	Unable to find full text or abstract, or trace authors

Characteristics of ongoing studies *[ordered by study ID]*

ACTRN12613000395730

Trial name or title	Investigating whether patients with ACS who receive a secondary-prevention educational resource have greater attendance at cardiac rehabilitation compared to patients who receive usual inpatient education
Methods	RCT
Participants	Patients aged over 18 years with a diagnosis of ACS and eligible for cardiac rehabilitation
Interventions	Patients will receive an educational booklet produced by the Heart Foundation Australia. The resource aims to support patients with coronary heart disease to understand and better manage their cardiac condition
Outcomes	Hospital admissions
Starting date	May 2013
Contact information	Dr Alison Beauchamp, Faculty of Health Deakin University Melbourne Burwood Campus, 221 Burwood Highway, Burwood, VIC 3125, Australia, alison.beauchamp@deakin.edu.au
Notes	http://www.anzctr.org.au/ACTRN12613000395730.aspx

ACTRN12613000793718

Trial name or title	TEXT messages to improve MEDication adherence & Secondary prevention in patients with acute coronary syndrome - TEXTMEDS
Methods	Parallel RCT
Participants	Acute coronary syndrome, a planned return to the community, ability to provide informed consent, own an operational mobile telephone and sufficient skill in English language to read and send text messages
Interventions	The intervention group will receive secondary prevention support program delivered via mobile phone text message and an opportunity to communicate with a health counsellor over a 12 month period. The messages will provide education, support, motivation and reminders with respect to medications and lifestyle
Outcomes	Major vascular event (cardiovascular death, non-fatal AMI, stroke or hospital admission with unstable angina or congestive heart failure), coronary revascularisation (coronary artery bypass graft surgery or percutaneous coronary intervention), Death, hospital readmission
Starting date	July 2013
Contact information	Assoc Prof Clara Chow, The George Institute for Global Health PO Box M201 Missenden Road NSW 2050, Australia , cchow@georgeinstitute.org.au
Notes	http://www.anzctr.org.au/ACTRN12613000793718.aspx

ACTRN12616000426482

Trial name or title	SMARTphone-based, early cardiac REHABilitation in patients with acute coronary syndromes: A Randomised Controlled Trial Protocol (SMART-REHAB Trial)
Methods	RCT
Participants	Adults with acute coronary syndromes with documented coronary artery disease
Interventions	The smartphone-based secondary prevention program delivered over 8 weeks starting at time of discharge from hospital through a smartphone application (App). This is a multi-faceted intervention with particular emphasis on early mobilisation. The app provides a platform to deliver a comprehensive secondary prevention program
Outcomes	Major adverse cardiovascular events (combination of death, mortality, stroke and unplanned revascularisation) , HRQoL, hospital readmissions
Starting date	04/04/2016
Contact information	Dr Matias Yudi, Austin Health Cardiology Department 145 Studley Road PO BOX 5555 Heidelberg, VIC 3084, Australia; matias.yudi@austin.org.au
Notes	Multi-faceted intervention, and not clear if the follow-up will extend beyond the duration of the 8 week intervention

Brewer 2015

Trial name or title	The Use of Virtual World-Based Cardiac Rehabilitation to Encourage Healthy Lifestyle Choices Among Cardiac Patients: Intervention Development and Pilot Study Protocol
Methods	In Phase 1: Patients will participate in a 12-week, virtual world health education program which will provide feedback on the feasibility, usability, and design of the intervention During Phase 2: A 2-arm, parallel group, single-centre, randomised controlled trial (RCT). Patients will be randomised at a 1:1 ratio to adjunct virtual world-based CR with conventional CR or conventional CR only
Participants	Patients recently hospitalised for an ACS (unstable angina, ST-segment elevation MI, non-ST-segment elevation MI) or who recently underwent elective PCI at Mayo Clinic Hospital, Rochester Campus in Rochester, Minnesota with at least one modifiable, lifestyle risk factor target (sedentary lifestyle, unhealthy diet, and current smoking)
Interventions	Adjunct virtual world-based CR with conventional CR or conventional CR only
Outcomes	The primary outcome is a composite including at least one of the following (1) at least 150 minutes of physical activity per week, (2) daily consumption of five or more fruits and vegetables, and (3) smoking cessation. Patients will be assessed at 3, 6, and 12 months
Starting date	NR
Contact information	Stephen Kopecky, Mayo Clinic College of Medicine, Department of Medicine, 200 First Street SW, Rochester, MN, 55905, United States, Phone: 1 507 284 9601, Fax: 1 507 266 0228, Email: ude.oyam@nehpets.

Brewer 2015 (*Continued*)

	ykcepok
Notes	

Dwinger 2013

Trial name or title	Telephone-based health coaching for chronically ill patients
Methods	The study is a prospective randomised controlled trial comparing the effects of telephone-based health coaching with usual care during a 4-year time period. Data are collected at baseline and after 12, 24 and 36 months. Patients are selected based on one of the following chronic conditions: diabetes, coronary artery disease, asthma, hypertension, heart failure, COPD, chronic depression or schizophrenia. The statistical analyses includes intention-to-treat and as-treated principles
Participants	Approximately 12,000 insurants will be enrolled
Interventions	The health coaching intervention is carried out by trained nurses employed by a German statutory health insurance. The frequency and the topics of the health coaching are manual-based but tailored to the patients' needs and medical condition, following the concepts of motivational interviewing, shared decision-making and evidence-based-medicine
Outcomes	Primary outcome is the time until hospital readmission within two years after enrolling in the health coaching, assessed by routine data. Secondary outcomes are patient-reported outcomes like changes in quality of life, depression and anxiety and clinical values assessed with questionnaires. Additional secondary outcomes are further economic evaluations like health service use as well as costs and hospital readmission rates
Starting date	The recruitment will be completed in September 2014
Contact information	Sarah Dwinger. Department of Medical Psychology, University Medical Center Hamburg-Eppendorf, Martinistr 52, Hamburg 20246, Germany. s.dwinger@uke.de
Notes	

IRCT201307162621N13

Trial name or title	The effects of application of Prochaska's stages of change model in education of coronary artery bypass grafting patients on quality of life, lipid profile & some psychological complications of CABG
Methods	RCT
Participants	Patients aged 40 to 75 who have received CABG
Interventions	Intervention group receive education based on stages of change model of Prochaska, for 8 weeks, immediately after discharge. Control group received "routine education"
Outcomes	Quality of life

IRCT201307162621N13 (*Continued*)

Starting date	February 2013
Contact information	Dr Marzieh Moattari, Faculty of Nursing and Midwifery, Namazi Square, Shiraz, Islamic Republic of Iran, moattarm@sums.ac.ir
Notes	

ISRCTN15839687

Trial name or title	A randomised controlled trial of the effectiveness of a self-help psycho-education programme on outcomes of outpatients with coronary heart disease
Methods	Single centre RCT
Participants	Patients aged 21 or more with a diagnosis of CHD, lives at home and does not intend to attend hospital-based rehabilitation programme
Interventions	Intervention group will receive a self-help psycho-education programme, which includes an education booklet, an accompanying DVD and an education session conducted by a member of the research team. Control group will receive usual care
Outcomes	Hospital admissions, HRQoL
Starting date	January 2015
Contact information	Wenru Wang, Alice Lee Centre for Nursing Studies Yong Loo Lin School of Medicine National University of Singapore 10, Medical Drive, Block MD11 Clinical Research Centre, Level 2 117597 Singapore Singaporewenru_wang@nuhs.edu.sg
Notes	

Kärner 2012

Trial name or title	COR-PRIM study NCT01462799
Methods	RCT
Participants	165 patients with CHD
Interventions	All patients will receive conventional care from their general practitioner and other care providers. The intervention consists of a patient education program in PHC by trained district nurses (tutors) who will apply PBL to groups of 6-9 patients meeting on 13 occasions for two hours over one year. Patients in the control group will not attend a PBL group but will receive home-sent patient information on 11 occasions during the year

Kärner 2012 (*Continued*)

Outcomes	The primary outcome is empowerment to reach self-care goals. Data collection will be performed at baseline at hospital and after one, three and five years in PHC using quantitative and qualitative methodologies involving questionnaires, medical assessments, interviews, diaries and observations
Starting date	September 2011
Contact information	anita.karner@liu.se; Department of Social and Welfare studies (HAV), Linköping University, Linköping, Sweden
Notes	"The first finding of the COR-PRIM study will become available in 2014, and the first results of the main study around 2015"

Lai 2016

Trial name or title	Patient and family satisfaction levels in the intensive care unit after elective cardiac surgery: study protocol for a randomised controlled trial of a preoperative patient education intervention
Methods	2-group, parallel, superiority, double-blinded randomised controlled trial
Participants	100 patients undergoing elective coronary artery bypass graft, with or without valve replacement surgery
Interventions	Participants will be randomised to either preoperative patient education comprising of a video and ICU tour with standard care (intervention) or standard education (control)
Outcomes	The primary outcome measures are the satisfaction levels of patients and family members with ICU care and decision-making in the ICU. The secondary outcome measures are patient anxiety and depression levels before and after surgery
Starting date	First received 26 Augst 2015
Contact information	Veronica Lai Ka Wai, veronicalai@link.cuhk.edu.hk
Notes	

Lynggaard 2014

Trial name or title	LC-REHAB NCT01668394
Methods	Open parallel randomised controlled trial conducted in three hospital units in Denmark
Participants	Patients recently discharged with ischemic heart disease or heart failure
Interventions	Patients are allocated to either the intervention group with learning and coping strategies incorporated into standard care in cardiac rehabilitation or the control group who receive the usual cardiac rehabilitation program. Learning and coping consists of two individual clarifying interviews, participation of experienced patients as educators together with health professionals and theory based, situated and inductive teaching.

Lynggaard 2014 (*Continued*)

	Usual care is characterised by a structured deductive teaching style with use of identical pre-written slides in all hospital units. In both groups, cardiac rehabilitation consists of training three times a week and education once a week over eight weeks
Outcomes	Adherence to cardiac rehabilitation, morbidity and mortality,quality of life (SF-12, Health education impact questionnaire and Major Depression Inventory) and lifestyle and risk factors (Body Mass Index, waist circumference, blood pressure, exercise work capacity, lipid profile and DXA-scan)
Starting date	30th of November 2010
Contact information	viblyn@rm.dk; Regional Hospital West Jutland, Cardiovascular Research Unit, Herning, Denmark
Notes	

NCT01028066

Trial name or title	Feeding Education in Patients Submitted to Coronary Angioplasty (PTCA-Nutri)
Methods	Open label RCT
Participants	Patients submitted for PTCA
Interventions	The intervention group will receive 4x 1 hour group meetings of food education, including Investigation, Contextualisation, Awareness and Strengthening the nutritional concepts.The control group will have access to the nutritionist
Outcomes	Cardiovascular event (new PTCA, CABG, ischemic acute syndrome, MI) and mortality (all causes) at 1 and 3 years
Starting date	April 2008
Contact information	Moacyr Roberto Cucê Nobre, Heart Institute, São Paulo University São Paulo, Brazil, 05403000
Notes	

NCT01275716

Trial name or title	Impact of Coronary Images Used During Patient Education on Coronary Artery Disease and Subsequent Lifestyle Modifications. Is a Picture Really Worth a Thousand Words?
Methods	RCT
Participants	Adults undergoing PCI for any clinical indication
Interventions	The investigators will show half of the patients their before and after images of their heart arteries where the narrowing occurred and was treated. The other half of the patients will not be shown these images

NCT01275716 (*Continued*)

Outcomes	Occurrence of major adverse cardiovascular events
Starting date	December 2010
Contact information	Janet Karol jkarol@uchicago.edu
Notes	

NCT01925079

Trial name or title	Intensive Education on Lipid Management
Methods	RCT
Participants	Patients ≥18 years, admitted with a diagnosis of ACS
Interventions	Multi-channel intensive patient education versus usual care
Outcomes	Major adverse cardiovascular events at 24 weeks follow up
Starting date	August 2013
Contact information	Bingqing Huang huang.bingqing@zs-hospital.sh.cn
Notes	

NCT02185391

Trial name or title	Interactive Education of Patients With Coronary Heart Disease (INSERT)
Methods	RCT
Participants	Patients ≥18 years with cardiovascular disease
Interventions	Using an Audience Response System (ARS) during oral presentations in rehabilitation centers to improve the learning effect of patients. Patients will receive motivating telephone calls in the follow-up
Outcomes	HRQoL, MI
Starting date	May 2014
Contact information	Paracelsus Harz Clinic Bad Suderode, Quedlinburg, Saxony-Anhalt, Germany, 06485
Notes	

NTR2388

Trial name or title	Evaluation Program "Coaching patients On Achieving Cardiovascular Health" (COACH)
Methods	Single site RCT
Participants	Patients with CHD (AMI or chronic/unstable angina), treated with a CABG, PCI or with medication and have finished the hospital's rehabilitation programme
Interventions	Trained professionals coach patients achieving targets of the influential risk factors, while focusing on lifestyle factors and drug use. Each session contains education, assertiveness training and goal setting
Outcomes	HRQoL
Starting date	June 2010
Contact information	Chantal Leemrijse, Postbus 1568 3500 BN Utrecht The Netherlands, C.Leemrijse@nivel.nl
Notes	http://www.trialregister.nl/trialreg/admin/rctview.asp?TC = 2388

Shah 2011

Trial name or title	SPRITE NCT00901277
Methods	3-arm RCT
Participants	450 patients with a recent MI and hypertension
Interventions	Telephone-based, nurse-administered disease management program. The first arm (N = 150) will receive home blood pressure (BP) monitors plus a nurse-delivered, telephone-based tailored patient education intervention and will be enrolled into HealthVault, a Microsoft electronic health record platform. The second arm (N = 150) will also receive BP monitors plus a tailored patient education intervention and be enrolled in HeartVault. However, the patient education intervention will be delivered by a Web-based program and will cover topics identical to those in the nurse-delivered intervention. Both arms will be compared with a control group receiving standard care (N = 150)
Outcomes	BP, LDL cholesterol, body weight, and glycosylated haemoglobin (in diabetic subjects), adherence to evidence-based therapies and improvement in health behaviours
Starting date	NR
Contact information	Bimal R. Shah, MD, MBA, Duke Clinical Research Institute, 2400 Pratt St, Durham, NC 27705; bimal.shah@duke.edu
Notes	

DATA AND ANALYSES

Comparison 1. Education versus no education

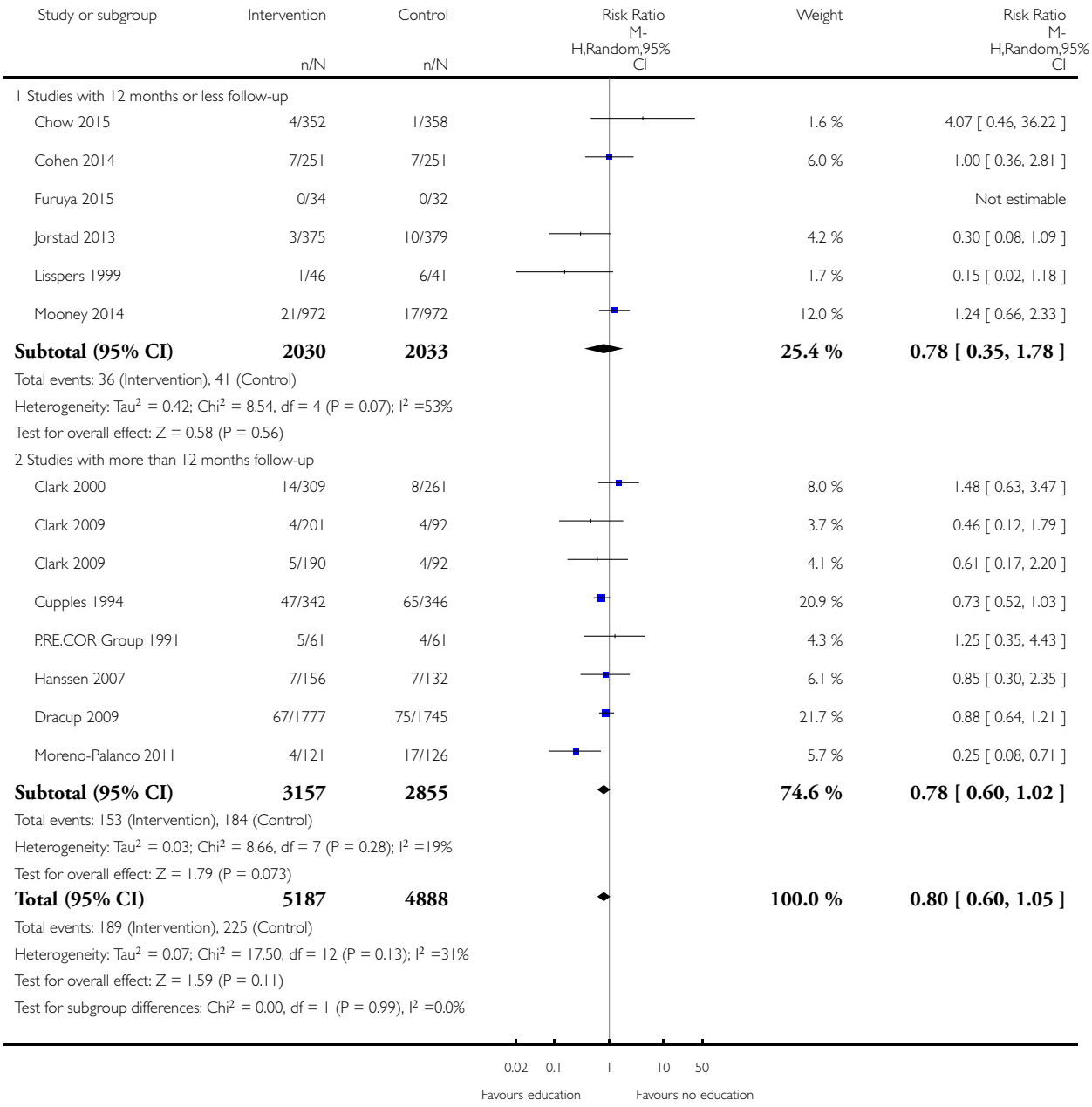
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Total mortality at the end of the follow up period	13	10075	Risk Ratio (M-H, Random, 95% CI)	0.80 [0.60, 1.05]
1.1 Studies with 12 months or less follow-up	6	4063	Risk Ratio (M-H, Random, 95% CI)	0.78 [0.35, 1.78]
1.2 Studies with more than 12 months follow-up	7	6012	Risk Ratio (M-H, Random, 95% CI)	0.78 [0.60, 1.02]
2 Fatal and/or non-fatal MI	2	209	Risk Ratio (M-H, Random, 95% CI)	0.63 [0.26, 1.48]
3 Other fatal and/or non-fatal cardiovascular events	2	310	Risk Ratio (M-H, Random, 95% CI)	0.36 [0.23, 0.56]
4 Total revascularisations (including CABG and PCI)	3	456	Risk Ratio (M-H, Random, 95% CI)	0.58 [0.19, 1.71]
5 Hospitalisations	5	14849	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.71, 1.21]
6 Withdrawals	17	10972	Risk Ratio (M-H, Random, 95% CI)	1.04 [0.88, 1.22]
6.1 Studies with 12 months or less follow-up	10	4960	Risk Ratio (M-H, Random, 95% CI)	1.18 [0.93, 1.49]
6.2 Studies with more than 12 months follow-up	7	6012	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.80, 1.20]

Analysis 1.1. Comparison 1 Education versus no education, Outcome 1 Total mortality at the end of the follow up period.

Review: Patient education in the management of coronary heart disease

Comparison: 1 Education versus no education

Outcome: 1 Total mortality at the end of the follow up period

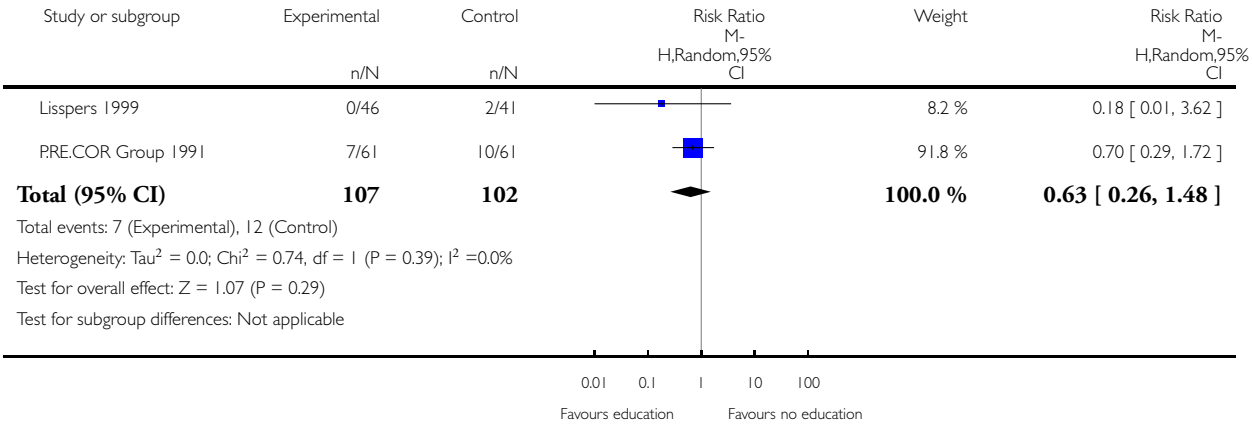


Analysis 1.2. Comparison 1 Education versus no education, Outcome 2 Fatal and/or non-fatal MI.

Review: Patient education in the management of coronary heart disease

Comparison: 1 Education versus no education

Outcome: 2 Fatal and/or non-fatal MI

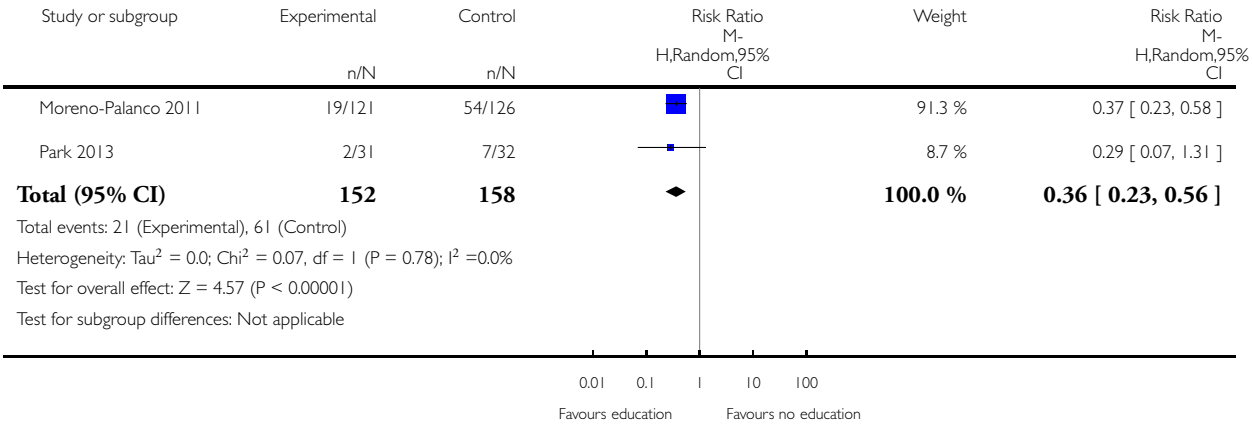


Analysis 1.3. Comparison 1 Education versus no education, Outcome 3 Other fatal and/or non-fatal cardiovascular events.

Review: Patient education in the management of coronary heart disease

Comparison: 1 Education versus no education

Outcome: 3 Other fatal and/or non-fatal cardiovascular events



Analysis 1.4. Comparison 1 Education versus no education, Outcome 4 Total revascularisations (including CABG and PCI).

Review: Patient education in the management of coronary heart disease

Comparison: 1 Education versus no education

Outcome: 4 Total revascularisations (including CABG and PCI)

Study or subgroup	Intervention n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Lisspers 1999	3/46	6/41		68.1 %	0.45 [0.12, 1.67]
Moreno-Palanco 2011	0/121	0/126			Not estimable
P.RE.COR Group 1991	2/61	2/61		31.9 %	1.00 [0.15, 6.87]
Total (95% CI)	**228**	**228**		**100.0 %**	**0.58 [0.19, 1.71]**

Total events: 5 (Intervention), 8 (Control)

Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.46$, df = 1 (P = 0.50); $I^2 = 0.0\%$

Test for overall effect: Z = 0.99 (P = 0.32)

Test for subgroup differences: Not applicable

Analysis 1.5. Comparison 1 Education versus no education, Outcome 5 Hospitalisations.

Review: Patient education in the management of coronary heart disease

Comparison: 1 Education versus no education

Outcome: 5 Hospitalisations

Study or subgroup	Intervention n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Esposito 2008	432/8821	184/3605		31.9 %	0.96 [0.81, 1.14]
Hanssen 2007	26/156	32/132		17.5 %	0.69 [0.43, 1.09]
Lisspers 1999	19/46	21/41		17.7 %	0.81 [0.51, 1.27]
Mooney 2014	177/972	137/972		30.1 %	1.29 [1.05, 1.59]
Southard 2003	2/53	7/51		2.8 %	0.27 [0.06, 1.26]
Total (95% CI)	**10048**	**4801**		**100.0 %**	**0.93 [0.71, 1.21]**

Total events: 656 (Intervention), 381 (Control)

Heterogeneity: $Tau^2 = 0.05$; $Chi^2 = 12.29$, df = 4 (P = 0.02); $I^2 = 67\%$

Test for overall effect: Z = 0.56 (P = 0.58)

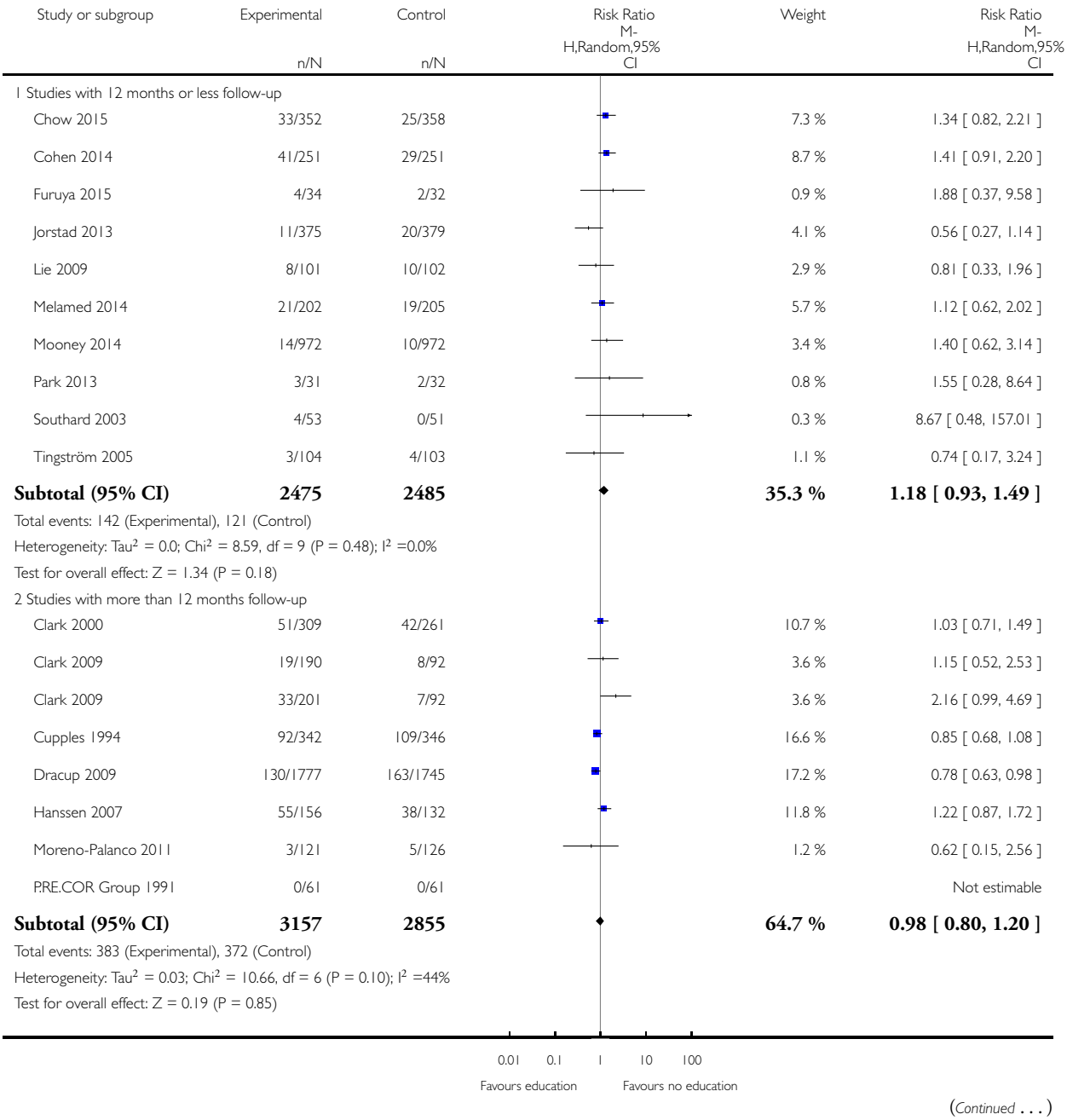
Test for subgroup differences: Not applicable

Analysis 1.6. Comparison 1 Education versus no education, Outcome 6 Withdrawals.

Review: Patient education in the management of coronary heart disease

Comparison: 1 Education versus no education

Outcome: 6 Withdrawals



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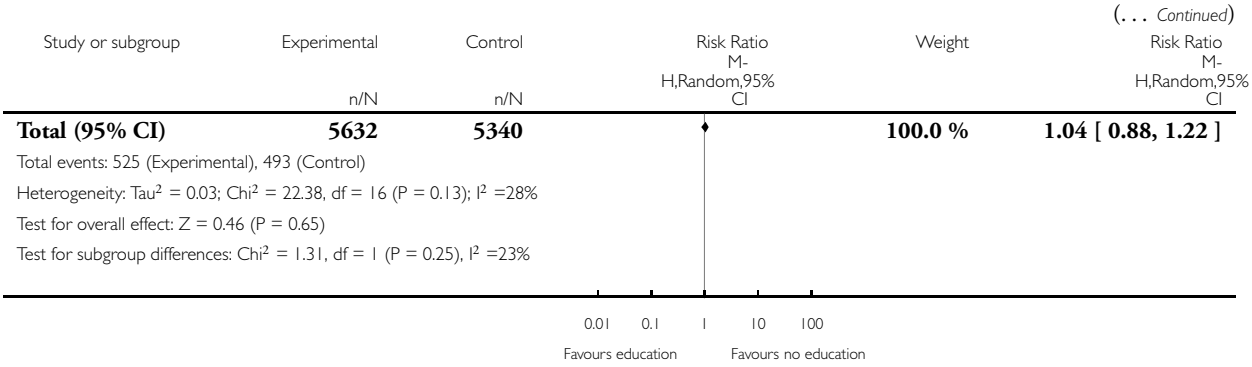

ADDITIONAL TABLES

Table 1. Results of sensitivity analysis for fixed-effect versus random-effects models

Outcome or subgroup	Studies	Participants	Effect estimate (random-effect) RR (M-H, random, 95% CI)	Effect estimate (fixed-effect) RR (M-H, fixed, 95% CI)
1.1 Total mortality at the end of the follow up period	13	10,075	0.80 [0.60, 1.05]	0.80 [0.66, 0.97]
1.1.1 Studies with 12 months or less follow-up	6	4063	0.78 [0.35, 1.78]	0.87 [0.56, 1.36]
1.1.2 Studies with more than 12 months follow-up	7	6012	0.78 [0.60, 1.02]	0.79 [0.64, 0.97]
2.1 Myocardial Infarction at the end of the follow-up period	2	209	0.63 [0.26, 1.48]	0.59 [0.25, 1.38]
2.2 Total revascularisations	3	456	0.58 [0.19, 1.71]	0.58 [0.20, 1.69]
2.3 Other fatal and/or non-fatal cardiovascular events	2	310	0.36 [0.23, 0.56]	0.36 [0.23, 0.56]
3.1 Cardiac hospitalisations at end of follow-up period	5	14,849	0.93 [0.71, 1.21]	1.02 [0.90, 1.15]

Table 1. Results of sensitivity analysis for fixed-effect versus random-effects models (*Continued*)

4.1 All cause withdrawal or drop-out at follow-up	17	10,972	1.04 [0.88, 1.22]	0.98 [0.88, 1.10]
4.1.1 Studies with 12 months or less follow-up	10	4960	1.18 [0.93, 1.49]	1.18 [0.94, 1.49]
4.1.2 Studies with more than 12 months follow-up	7	6012	0.98 [0.80, 1.20]	0.92 [0.81, 1.05]

Table 2. Educational content of programs in included studies

Study ID	Description of Intervention	Theoretical basis	Tailored	Duration	One-to-one	Group	Face- to-face	Telephone	Internet	Notes
Chow 2015	Text message-based prevention program delivering regular semi-personalised messages providing advice, motivation, and information to improve diet, increase physical activity, and encourage smoking cessation	NR	Y	4 messages per week for 24 weeks	Y	N	N	Y (text messages)	N	Content for each participant was selected using a pre-specified algorithm dependent on key baseline characteristics
Clark 1997	*PRIDE	Y	Y	Once weekly for 4		Y	Y			Taught by health educator.

Table 2. Educational content of programs in included studies (*Continued*)

				weeks						Videotape and workbook aids
Clark 2000	*PRIDE	Y	Y	Once weekly for 4 weeks		Y	Y			Taught by health educator. Videotape and workbook aids
Clark 2009	*PRIDE	Y	Y	Once weekly for 6 weeks	Y	Y	Y			3 groups (self-directed and group intervention and a control)
Cohen 2014	"House of Education" with individualised consultations with e.g. smoking cessation nurse	NR	Y	At least 6 sessions in 12 months	Y	N	Y	N	N	Consultations content was individualised according to a patient's risk factors
Cupples 1994	Practical tailored advice on cardiovascular risk factors and appropriate health education	NR	Y	3 times a year for 2 years	Y		Y			Delivered at home by health visitor
Dracup 2009	Patients received education on ACS, anticipated	Y	Y	55 mins (40 min face-to-face plus 15 min	Y	N	Y	N	N	Delivered by a nurse with expertise in cardiology

Table 2. Educational content of programs in included studies (*Continued*)

	emotional issues and social factors that could affect delay			follow-up call)						
Esposito 2008	Predesigned scripts to provide education on various aspects of care, geared to personalised clinical goals	NR	Y	Average 1.1 contacts per month for 18 months	Y		Y	Y		Nurse case manager, primarily by telephone but also face-to-face
Furuya 2015	Three booklets and three telephone follow-up calls aimed at helping patient understand his cardiac condition, PCI and how to cope with CAD	Y	N	2 face to face sessions and 3 telephone calls over 16 weeks	Y	N	Y	Y	N	The first booklet was discussed with participants before undergoing PCI procedure
Hanssen 2007	Individualised education from a menu of topics to be cov-	Y	Y	6 months (8 sessions in total)	Y			Y		Structured element and an on-call element

Table 2. Educational content of programs in included studies (*Continued*)

	ered									
Jorstad 2013	Outpatient clinic visits to a cardiovascular nurse	NR	Y	6 months (4 sessions)	NR	NR	Y	N	N	Nurse-coordinated: provided general lifestyle advice, and individual counselling
Lie 2009	A psychoeducative intervention. Structured information and psychological support	NR	N/S	2 visits (1 hour each)	Y		Y			Critical care nurse, home based
Lisspers 1999	Health education and achievement of behavioural change	NR	Y	4 week residential then 11 month one-to-one individual sessions	Y	Y	Y			Trained nurses (personal coaches) . Seminars, lectures, discussion and skills sessions
Melamed 2014	Lesson materials consisted of a patient brochure, teaching cards and curriculum poster/ wall chart set	NR	N	NR	Y	N	Y	N	N	Patients were given an exercise diary to enable them to document their daily physical activity
Mooney 2014	Education interven-	Y	Y	6 months (1 face-	Y	N	Y	Y	N	Research nurses used

Table 2. Educational content of programs in included studies (*Continued*)

	tion aimed at reducing total pre-hospital delay time			to-face session, 1 telephone call and one reinforcement letter at 6 months)						preprinted flip charts and prescriptive scripts as educational aids
Moreno-Palanco 2011	Health education on the meaning of patients' disease and the importance of treatment	NR	NR	3 years (at least 5 sessions)	Y	N	Y	N	N	Each visit consisted of a nursing intervention and a medical assessment
P.RE.COR Group 1991	Education and counselling on management of cardiovascular risk factors and exercise	NR	Y	1 group session, 1 individual session with cardiologist	Y	Y	Y			Multidisciplinary input to group. Cardiologist tailors therapy
Park 2013	Psychoeducational intervention comprising tailored face-to-face education and telephone-delivered health	NR	Y	12 weeks (6 sessions)	Y	N	Y	Y	N	Patients made choices about risk factors they wanted to lower and participated in goal setting

Table 2. Educational content of programs in included studies (*Continued*)

	coaching									
Peikes 2009	Variable - nurse provision of patient education	NR	NR	1 to 2.5 times a month for an average of 30 months	Y			Y		15 different programs, majority telephone, one-to-one
Pogosova 2008	Structured program addressing different risk factors in each session	Y	NR	6 sessions (twice weekly, 90 min)		Y	Y			
Southard 2003	Modular internet sessions, Interactive multiple choice and self tests followed by feedback	NR	NR	Once weekly for 6 months (at least 30 min)	Y	Y			Y	Communication with case manager and online discussion group
Tingström 2005	Problem based rehabilitation to teach a planned curriculum	Y	NR	13 sessions over 1 year		Y	Y			Trained facilitator

PRIDE = Problem Identification, Researching one's routine, Identifying a management goal, Developing a plan to reach it, Expressing one's reactions and Establishing rewards for making progress.

Y = Yes; N = No; NR = not reported

Table 3. All-cause withdrawal or drop-out at follow-up

Study ID		Number randomised	Number lost at follow-up*	Notes
Chow 2015	Intervention	352	33	20 excluded from analysis, 9 unable to contact, 4 died
	Control	358	25	21 excluded from analysis, 3 unable to contact, 1 died
Clark 2000	Intervention	309	51	36 withdrew, 14 died, 1 data missing
	Control	262	42	33 withdrew, 8 died, 1 data missing
Clark 2009	Intervention	201	37	Self-directed program; 33 withdrew, 4 died
	Intervention	190	24	Group format; 19 withdrew, 5 died
	Control	184	23	15 withdrew, 8 died
Cohen 2014	Intervention	251	48	6 did not meet inclusion criteria, 7 died, 23 follow-up refusal, 10 lost to follow-up, 2 in another protocol
	Control	251	36	4 did not meet inclusion criteria, 7 died, 13 follow-up refusal, 12 lost to follow-up
Cupples 1994	Intervention	342	92	45 defaulted, 47 died; 21 defaulted at 2 years
	Control	346	109	44 defaulted, 65 died; 25 defaulted at 2 years
Dracup 2009	Intervention	1777	197	89 lost to follow-up, 41 withdrawn, 67 died
	Control	1745	238	94 lost to follow-up, 69 withdrawn, 75 died
Furuya 2015	Intervention	34	4	4 unable to contact by telephone at follow-up (90 participants were originally randomised (45 in each group), but 24 participants were ex-

Table 3. All-cause withdrawal or drop-out at follow-up (*Continued*)

				cluded immediately after randomisation as they were indicated for surgery or enrolled in another study)
	Control	32	2	2 did not return for 6 month follow-up
Hanssen 2007	Intervention	156	55	40 withdrew, 7 died, 8 missing data
	Control	132	38	21 withdrew, 7 died, 10 missing data
Jorstad 2013	Intervention	375	23	9 did not receive intervention, 3 died, 2 had early discontinuation of intervention, 9 had incomplete data
	Control	379	35	12 were excluded from the study, 10 died, 1 lost to follow-up, 7 didn't attend 12 month follow-up, 5 had incomplete data
Lie 2009	Intervention	101	8	6 withdrew, 2 medical exclusions
	Control	102	10	5 withdrew, 5 medical exclusions
Melamed 2014	Intervention	202	21	"patients were exclude (for example, because of missed training appointments)"
	Control	205	19	"patients were excluded (for example, because of missed training appointments)"
Mooney 2014	Intervention	972	35	14 withdrew, 21 died
	Control	972	27	10 withdrew, 17 died
Moreno-Palanco 2011	Intervention	121	3	3 lost to follow-up, 0 died
	Control	126	5	5 lost to follow-up, 0 died
P.RE.COR Group 1991	Intervention	60	0	Counseling program without exercise
	Intervention	61	0	Comprehensive cardiac rehabilitation

Table 3. All-cause withdrawal or drop-out at follow-up (*Continued*)

	Control	61	0	Usual care
Park 2013	Intervention	31	3	3 withdrew, 0 died
	Control	32	2	2 withdrew, 0 died
Southard 2003	Intervention	53	4	Reasons for drop-out stated: relocation, dietary intervention instead, psychiatric diagnosis, loss of interest
	Control	51	0	
Tingström 2005	Intervention	104	3	7 lost to follow-up: 2 died, 5 did not attend
	Control	103	4	
Combined results	**Intervention**	5692	641	11.3%
	Control	5341	615	11.5%

* All causes of drop out from follow0up included (including mortality)

Table 4. Summary of HRQoL scores at follow-up: Clark 1997

Sickness Impact Profile+++ at 12 months				
	Absolute mean outcome values at follow-up++			**Comparison**
	Education	**Comparator**	**Between group P value**	
Clark 1997(12 months)				
Total score	7.26	8.09	NS	Education = comparator
Psychosocial dimension	5.52	7.05	≤ 0.05	**Education > comparator**
Physical dimension	5.89	6.00	NS	Education = comparator
Sickness Impact Profile+++ at 18 months				
	Absolute mean outcome values at follow-up++			**Comparison**
	Education	**Comparator**	**Between group P value**	
Total score	7.93	7.41	NS	Education = comparator
Psychosocial dimension	6.05	6.23	NS	Education = comparator

Table 4. Summary of HRQoL scores at follow-up: Clark 1997 (*Continued*)

Physical dimension	6.40	5.25	NS	Education = comparator

++ for mean scores at follow-up (adjusted for baseline scores)
+++ lower score higher HRQoL
NS: No significant difference demonstrated
Education = Comparator: no significant difference (P > 0.05) in HRQoL between the education and the comparator groups at follow-up.
Education > Control: significant difference (P ≤ 0.05) in HRQoL in favour of the education group at follow-up.
Comparator > Education: significant difference (P ≤ 0.05) in HRQoL in favour of the comparator group at follow-up.
Favours education: Available evidence favours the intervention group but direct statistical comparison between intervention and control groups was not reported.
Favours comparator: Available evidence favours the control group but direct statistical comparison between intervention and control groups was not reported.

Table 5. Summary of HRQoL scores at follow-up: Clark 2000

Sickness Impact Profile at 12 months				
Clark 2000(12 months)	**Absolute means at follow-up++**			**Comparison**
	Education	**Comparator**	**Between group P value**	
Psychosocial dimension	5.15	5.91	0.144	Education = comparator
Physical dimension	7.09	7.66	0.05	**Education > comparator**

Means were adjusted to take account of baseline values
NS: No significant difference demonstrated
Education = Comparator: no significant difference (P > 0.05) in HRQoL between the education and the comparator groups at follow-up.
Education > Control: significant difference (P ≤ 0.05) in HRQoL in favour of the education group at follow-up.
Comparator > Education: significant difference (P ≤ 0.05) in HRQoL in favour of the comparator group at follow-up.
Favours education: Available evidence favours the intervention group but direct statistical comparison between intervention and control groups was not reported.
Favours comparator: Available evidence favours the control group but direct statistical comparison between intervention and control groups was not reported.

Table 6. Summary of HRQoL scores at follow-up: Clark 2009

Sickness Impact Profile at 12 months		
	Absolute means (SD) at follow-up	**Comparison**

Table 6. Summary of HRQoL scores at follow-up: Clark 2009 (*Continued*)

	Education	Education self directed	Comparator	Between group P value	
Total score	8.13 (8.63)	9.79 (10.17)	9.49 (9.46)	NS	Education = comparator
Psychosocial dimension	5.84 (8.02)	7.31 (10.74)	6.75 (9.39)	NS	Education = comparator
Physical dimension	8.07 (9.63)	9.46 (10.11)	9.85 (10.79)	NS	Education = comparator
Sickness Impact Profile at 18 months					
Total score	8.44 (9.13)	8.98 (10.29)	9.64 (9.45)	NS	Education = comparator
Psychosocial dimension	5.74 (9.68)	6.16 (8.20)	7.17 (10.40)	NS	Education = comparator
Physical dimension	8.27 (10.02)	8.98 (9.33)	9.65 (10.19)	NS	Education = comparator

Note: analysis of these data was reported, but the individual results were not. These were obtained by contacting the author directly
NS: No significant difference demonstrated
Education = Comparator: no significant difference (P > 0.05) in HRQoL between the education and the comparator groups at follow-up.
Education > Control: significant difference (P ≤ 0.05) in HRQoL in favour of the education group at follow-up.
Comparator > Education: significant difference (P ≤ 0.05) in HRQoL in favour of the comparator group at follow-up.
Favours education: Available evidence favours the intervention group but direct statistical comparison between intervention and control groups was not reported.
Favours comparator: Available evidence favours the control group but direct statistical comparison between intervention and control groups was not reported.

Table 7. Summary of HRQoL scores at follow-up: Cohen 2014

SF-12 (Short Form 12 item survey) at 6 months				
	Mean (SD) outcome values at follow-up		**Between group P value**	**Comparison**
	Education	**Comparator**		
Mental component summary	47.5 (11.2)	47.7 (11.2)	0.43	Education = comparator

Table 7. Summary of HRQoL scores at follow-up: Cohen 2014 (*Continued*)

Physical component summary	47.5 (9.3)	47.3 (9.4)	0.44	Education = comparator

Negative baseline-follow-up difference favours intervention and positive favours control
NS: No significant difference demonstrated
Education = Comparator: no significant difference (P > 0.05) in HRQoL between the education and the comparator groups at follow-up.
Education > Control: significant difference (P ≤ 0.05) in HRQoL in favour of the education group at follow-up.
Comparator > Education: significant difference (P ≤ 0.05) in HRQoL in favour of the comparator group at follow-up.
Favours education: Available evidence favours the intervention group but direct statistical comparison between intervention and control groups was not reported.
Favours comparator: Available evidence favours the control group but direct statistical comparison between intervention and control groups was not reported.

Table 8. Summary of HRQoL scores at follow-up: Cupples 1994

Nottingham Health Profile+ at 24 months			
	MD (95% CI) between groups in change from baseline at follow-up	**Between group P value**	**Comparison**
Emotional reaction	0.0 (-5.2 to 5.2)	NS	Education = comparator
Energy	0.5 (-7.8 to 8.8)	NS	Education = comparator
Physical mobility	-0.4 (-5.2 to 4.5)	NS	Education = comparator
Pain	0.5 (-4.7 to 5.6)	NS	Education = comparator
Sleep	3.0 (-4.0 to 9.9)	NS	Education = comparator
Social isolation	-2.2 (-6.6 to 2.1)	P < 0.05	**Education > comparator**
Nottingham Health Profile+ at 60 months			
	MD (95% CI) between groups in change from baseline at follow-up	**Between group P value**	**Comparison**
Emotional reaction	-2.1 (-7.5 to 3.3)	NS	Education = comparator
Energy	-4.7 (-13.2 to 3.7)	NS	Education = comparator
Physical mobility	-1.3 (-6.3 to 3.6)	< 0.05	**Education > comparator**

Table 8. Summary of HRQoL scores at follow-up: Cupples 1994 (*Continued*)

Pain	-3.4 (-9.2 to 2.3)	< 0.05	**Education > comparator**
Sleep	-2.4 (-9.3 to 4.5)	NS	Education = comparator
Social isolation	0.0 (-4.3 to 4.3)	NS	Education = comparator

+ Higher scores reflect poorer quality of life
The value quoted is the mean difference (MD) (CI) between groups from baseline to follow-up
P related to t-tests (two tailed)
NS: No significant difference demonstrated
Education = Comparator: no significant difference (P > 0.05) in HRQoL between the education and the comparator groups at follow-up.
Education > Control: significant difference (P ≤ 0.05) in HRQoL in favour of the education group at follow-up.
Comparator > Education: significant difference (P ≤ 0.05) in HRQoL in favour of the comparator group at follow-up.
Favours education: Available evidence favours the intervention group but direct statistical comparison between intervention and control groups was not reported.
Favours comparator: Available evidence favours the control group but direct statistical comparison between intervention and control groups was not reported.

Table 9. Summary of HRQoL scores at follow-up: Cupples 1994

Participant' self assessment of quality of life on a five-point scale at 24 months						
	Initial scores (% participants)		**Follow-up scores (% participants)**		**Between group P value**	**Comparison**
	Education	**Comparator**	**Education**	**Comparator**		
					P < 0.03	**Education > comparator**
Poor	6.3	5.3	6.9	8.3		
Fair	27.8	23.3	18.9	21.7		
Average	35	39	33.1	33.7		
Good	22.7	22.7	29.3	25.3		
Very good	8.2	9.7	11.7	11		

Note: the between group P value represents the overall "comparison of change in individuals' assessment for intervention and control groups" the significant difference being in favour of the intervention group
NS: No significant difference demonstrated
Education = Comparator: no significant difference (P > 0.05) in HRQoL between the education and the comparator groups at follow-up.
Education > Control: significant difference (P ≤ 0.05) in HRQoL in favour of the education group at follow-up.

Comparator > Education: significant difference (P ≤ 0.05) in HRQoL in favour of the comparator group at follow-up.
Favours education: Available evidence favours the intervention group but direct statistical comparison between intervention and control groups was not reported.
Favours comparator: Available evidence favours the control group but direct statistical comparison between intervention and control groups was not reported.

Table 10. Summary of HRQoL scores at follow-up: Furuya 2014

SF-12* (Short Form 12 item survey) at 6 months				
	Mean (SD) outcome values at follow-up		**Between group P value**	**Comparison**
	Education	**Comparator**		
Mental component summary	51.7 (9.5)	48.4 (9.2)	0.73	Education = comparator
Physical component summary	43.3 (10.6)	41.0 (11.0)	0.28	Education = comparator
SF-36* (Short Form 36 item survey)				
	Mean (SD) outcome values at follow-up		**Between group P value**	**Comparison**
	Education	**Comparator**		
Social functioning	79.2 (25.1)	64.2 (28.4)	0.1	Education = comparator
Mental health	70.9 (22.7)	70.1 (19.1)	0.98	Education = comparator
Physical functioning	72.5 (23.9)	64.5 (27.8)	0.2	Education = comparator
General health	66.1 (19.8)	63.9 (20.0)	0.61	Education = comparator
Vitality	69.7 (20.6)	62.5 (20.7)	0.52	Education = comparator
Bodily pain	63.8 (28.5)	55.7 (24.2)	0.22	Education = comparator
Role-emotional	77.8 (36.4)	64.4 (36.0)	0.72	Education = comparator
Role-physical	52.5 (40.7)	50.0 (44.0)	0.96	Education = comparator

*Negative baseline - follow-up difference favours intervention; positive difference favours control
NS: No significant difference demonstrated
Education = Comparator: no significant difference (P > 0.05) in HRQoL between the education and the comparator groups at follow-up.
Education > Control: significant difference (P ≤ 0.05) in HRQoL in favour of the education group at follow-up.
Comparator > Education: significant difference (P ≤ 0.05) in HRQoL in favour of the comparator group at follow-up.

Favours education: Available evidence favours the intervention group but direct statistical comparison between intervention and control groups was not reported.
Favours comparator: Available evidence favours the control group but direct statistical comparison between intervention and control groups was not reported.

Table 11. Summary of HRQoL scores at follow-up: Hanssen 2007

SF-36* (Short Form 36 item survey) at 6 months			
	Between group difference in mean change from baseline (95% CI) at follow-up	**Between group P value**	**Comparison**
Overall physical	-2.33 (-4.54 to -0.12)	0.039	Education = comparator
Physical functioning	-1.16 (-3.28 to 0.95)	0.28	Education = comparator
Role physical	-1.84 (-5.32 to 1.64)	0.299	Education = comparator
Bodily pain	-1.74 (-4.54 to 1.05)	0.22	Education = comparator
General health	-0.36 (-2.64 to 1.91)	0.752	Education = comparator
Overall mental	1.07 (-1.71 to 3.86)	0.447	Education = comparator
Vitality	-0.07 (-2.23 to 2.10)	0.951	Education = comparator
Social functioning	0.36 (-2.96 to 3.67)	0.832	Education = comparator
Role-emotional	0.78 (-3.29 to to 4.84)	0.706	Education = comparator
Mental health	0.4 (-1.81 to 2.60)	0.723	Education = comparator
SF-36* (Short Form 36 item survey) at 18 months			
	Between group difference in mean change from baseline (95% CI) at follow-up	**Between group P value**	**Comparison**
Overall physical	-1.44 (-3.89 to 1.02)	0.25	Education = comparator
Physical functioning	-0.79 (-3.06 to 1.48)	0.491	Education = comparator
Role physical	-0.94 (-4.76 to 2.88)	0.627	Education = comparator
Bodily pain	-0.77 (-4.00 to 2.47)	0.641	Education = comparator
General health	0.25 (-2.15 to 2.64)	0.838	Education = comparator

Table 11. Summary of HRQoL scores at follow-up: Hanssen 2007 (*Continued*)

Overall mental	1.65 (-1.35 to 4.65)	0.28	Education = comparator
Vitality	0.58 (-1.95 to 3.12)	0.65	Education = comparator
Social functioning	0.55 (-3.95 to 2.85)	0.751	Education = comparator
Role-emotional	2.59 (-1.58 to 6.77)	0.221	Education = comparator
Mental health	0.31 (-2.11 to 2.73)	0.8	Education = comparator

*Negative baseline - follow-up difference favours intervention; positive difference favours control
NS: No significant difference demonstrated
Education = Comparator: no significant difference (P > 0.05) in HRQoL between the education and the comparator groups at follow-up.
Education > Control: significant difference (P ≤ 0.05) in HRQoL in favour of the education group at follow-up.
Comparator > Education: significant difference (P ≤ 0.05) in HRQoL in favour of the comparator group at follow-up.
Favours education: Available evidence favours the intervention group but direct statistical comparison between intervention and control groups was not reported.
Favours comparator: Available evidence favours the control group but direct statistical comparison between intervention and control groups was not reported.

Table 12. Summary of HRQoL scores at follow-up: Lie 2009

Seattle Angina Questionnaire at 6 months					
	Absolute mean (SD) outcome values at follow-up				**Comparison**
	Education	**P value**	**Comparator**	**P value**	
Physical limitation	86.4 (15.6)	P < 0.001	83.2 (18.7)	P < 0.001	Education = comparator
Angina frequency	91.7 (16.6)	P < 0.001	90.8 (18.9)	P < 0.001	Education = comparator
Treatment satisfaction	89.2 (15.4)	NS	88.0 (16.1)	NS	Education = comparator
Disease perception	77.8 (20.2)	P < 0.001	73.9 (24.2)	P < 0.001	Education = comparator
SF-36 (Short Form 36 item survey) at 6 months					
	Absolute mean (SD) outcome values at follow-up				**Comparison**
	Education	**P value**	**Comparator**	**P value**	
Overall physical	47.4 (9.6)	P < 0.001	47 (10)	P < 0.001	Education = comparator

Table 12. Summary of HRQoL scores at follow-up: Lie 2009 (*Continued*)

Physical functioning	82.2 (19.2)	P < 0.001	82.3 (19.8)	P < 0.001	Education = comparator
Role physical	64 (41.2)	P < 0.001	57.2 (43.3)	P < 0.001	Education = comparator
Bodily pain	77.2 (22.3)	P < 0.001	78.5 (25.2)	P < 0.001	Education = comparator
General health	69.9 (23.3)	NS	65.7 (27.2)	NS	Education = comparator
Overall mental	52.1 (10.7)	P < 0.05	50.5 (10.8)	NS	**Favours education**
Vitality	61.9 (23.9)	P < 0.001	60.5 (21.6)	P < 0.001	Education = comparator
Social functioning	86.3 (21.4)	P < 0.001	84.3 (21.9)	P < 0.001	Education = comparator
Role- emotional	73.3 (38.2)	P < 0.01	67.4 (41.6)	P < 0.01	Education = comparator
Mental health	81.9 (17.3)	P < 0.001	78.5 (21)	P < 0.01	Education = comparator

Higher scores indicate better HRQoL
NS: No significant difference demonstrated
Education = Comparator: no significant difference (P > 0.05) in HRQoL between the education and the comparator groups at follow-up.
Education > Control: significant difference (P ≤ 0.05) in HRQoL in favour of the education group at follow-up.
Comparator > Education: significant difference (P ≤ 0.05) in HRQoL in favour of the comparator group at follow-up.
Favours education: Available evidence favours the intervention group but direct statistical comparison between intervention and control groups was not reported.
Favours comparator: Available evidence favours the control group but direct statistical comparison between intervention and control groups was not reported.

Table 13. Summary of HRQoL scores at follow-up: Lisspers 1999

Angina Pectoris - Quality of Life Questionnaire (AP-QLQ) at 24 months				
	Mean (SD) score at follow-up		**Between group P value**	**Comparison**
	Education	**Comparator**		
QLQ (total)	4.7 (0.8)	4.3 (1.0)	NS	Education = comparator
Somatic symptoms	4.8 (1.0)	4.3 (1.1)	NS	Education = comparator
Physical activity	4.8 (1.0)	4.1 (1.2)	NS	Education = comparator
Emotional distress	4.8 (0.8)	4.6 (1.1)	NS	Education = comparator

Table 13. Summary of HRQoL scores at follow-up: Lisspers 1999 (*Continued*)

Life satisfaction	4.2 (1.0)	3.9 (1.2)	NS	Education = comparator

Figures quoted represent absolute scores on a self-rating scale
NS: No significant difference demonstrated
Education = Comparator: no significant difference (P > 0.05) in HRQoL between the education and the comparator groups at follow-up.
Education > Control: significant difference (P ≤ 0.05) in HRQoL in favour of the education group at follow-up.
Comparator > Education: significant difference (P ≤ 0.05) in HRQoL in favour of the comparator group at follow-up.
Favours education: Available evidence favours the intervention group but direct statistical comparison between intervention and control groups was not reported.
Favours comparator: Available evidence favours the control group but direct statistical comparison between intervention and control groups was not reported.

Table 14. Summary of HRQoL scores at follow-up: Melamed 2014

MacNew Heart Disease Quality of Life Questionnaire (MacNew) at 220 days				
	Mean (SD) outcome values at follow-up		**Between group P value**	**Comparison**
	Education	**Comparator**		
Rank sum	5.75 (0.87)	5.74 (0.83)	0.056	Education = comparator

NS: No significant difference demonstrated
Education = Comparator: no significant difference (P > 0.05) in HRQoL between the education and the comparator groups at follow-up.
Education > Control: significant difference (P ≤ 0.05) in HRQoL in favour of the education group at follow-up.
Comparator > Education: significant difference (P ≤ 0.05) in HRQoL in favour of the comparator group at follow-up.
Favours education: Available evidence favours the intervention group but direct statistical comparison between intervention and control groups was not reported.
Favours comparator: Available evidence favours the control group but direct statistical comparison between intervention and control groups was not reported.

Table 15. Summary of HRQoL scores at follow-up: Park 2013

Seattle Angina Questionnaire-Korean (SAQ-K) at 6 months				
	Mean (SD) outcome values at follow-up		**Between group P value**	**Comparison**
	Education	**Comparator**		
Physical symptoms				
Physical limitation	90.77 (9.97)	85.74 (15.37)	0.901	Education = comparator

Table 15. Summary of HRQoL scores at follow-up: Park 2013 (*Continued*)

Angina stability	78.57 (20.09)	64.17 (23.38)	0.037	**Education > comparator**
Angina frequency	94.29 (7.90)	89.33 (14.84)	0.543	Education = comparator
Treatment satisfaction	86.38 (12.15)	73.13 (16.09)	0.021	**Education > comparator**
Diseases perception	74.40 (16.03)	52.78 (15.98)	0.005	**Education > comparator**

Higher scores indicate better HRQoL
NS: No significant difference demonstrated
Education = Comparator: no significant difference (P > 0.05) in HRQoL between the education and the comparator groups at follow-up.
Education > Control: significant difference (P ≤ 0.05) in HRQoL in favour of the education group at follow-up.
Comparator > Education: significant difference (P ≤ 0.05) in HRQoL in favour of the comparator group at follow-up.
Favours education: Available evidence favours the intervention group but direct statistical comparison between intervention and control groups was not reported.
Favours comparator: Available evidence favours the control group but direct statistical comparison between intervention and control groups was not reported.

Table 16. Summary of HRQoL scores at follow-up: Pogosova 2008

SF-36 (Short Form 36 item survey) at 12 months			
	Mean change from baseline P value		**Comparison**
	Education	**Comparator**	
Overall physical	P > 0.05	P ≤ 0.05	**Favours education**
Physical functioning	P > 0.05	P ≤ 0.05	**Favours education**
Bodily pain	P > 0.05	P ≤ 0.05	**Favours education**
Overall mental	P > 0.05	P ≤ 0.05	**Favours education**
Vitality	P > 0.05	P ≤ 0.05	**Favours education**
Social functioning	P > 0.05	P ≤ 0.05	**Favours education**
Mental health	P > 0.05	P ≤ 0.05	**Favours education**

There were no significant changes demonstrated in the control group but no statistical comparison of the mean change between groups was reported
NS: No significant difference demonstrated
Education = Comparator: no significant difference (P > 0.05) in HRQoL between the education and the comparator groups at follow-up.
Education > Control: significant difference (P ≤ 0.05) in HRQoL in favour of the education group at follow-up.

Comparator > Education: significant difference (P ≤ 0.05) in HRQoL in favour of the comparator group at follow-up.
Favours education: Available evidence favours the intervention group but direct statistical comparison between intervention and control groups was not reported.
Favours comparator: Available evidence favours the control group but direct statistical comparison between intervention and control groups was not reported.

Table 17. Summary of HRQoL scores at follow-up: Tingström 2005

SF-36* (Short Form 36 item survey) at 12 months				
	Mean change from baseline (SD)		Between group P value+	Comparison
	Education	Comparator		
Physical functioning	3.6 (17.6)	4.4 (15.1)	0.749	Education = comparator
Role physical	38.2 (46.9)	33.8 (42.4)	0.504	Education = comparator
Bodily pain	5.69 (31.1)	6.18 (29.1)	0.911	Education = comparator
General health	1.4 (15.9)	1.8 (16.3)	0.862	Education = comparator
Vitality	5.3 (22.7)	4.9 (21.8)	0.921	Education = comparator
Social functioning	9.7 (24)	9.1 (25.3)	0.869	Education = comparator
Role emotional	15.8 (48.1)	16.5 (41.1)	0.913	Education = comparator
Mental health	2.9 (16.6)	4.2 (17.8)	0.566	Education = comparator

*Positive values indicate improvement in HRQL from baseline
+ P values are calculated on the difference between groups at pre-test and on the mean change (post test minus pre-test).
NS: No significant difference demonstrated
Education = Comparator: no significant difference (P > 0.05) in HRQoL between the education and the comparator groups at follow-up.
Education > Control: significant difference (P ≤ 0.05) in HRQoL in favour of the education group at follow-up.
Comparator > Education: significant difference (P ≤ 0.05) in HRQoL in favour of the comparator group at follow-up.
Favours education: Available evidence favours the intervention group but direct statistical comparison between intervention and control groups was not reported.
Favours comparator: Available evidence favours the control group but direct statistical comparison between intervention and control groups was not reported.

Table 18. Cost summary of intervention and comparison of healthcare costs incurred by intervention and control groups during follow-up period

Variable	Clark 2000	Cupples 1994	Esposito 2008				Southard 2003	Peikes 2009
Follow-up	24 months	24 months	6 months	7 to 12 months	12 months	18 months	6 months	25 months
Year	2000	NR	2005 to 2006				NR	2002 to 2005
Currency	USD	GBP	USD				USD	USD
Mean cost of cardiac rehabilitation program per patient								
Total costs	USD 187	GBP 49.72	USD 162				USD 453	USD 196
Costs considered	Personnel, instructional materials, telephone supplies, ongoing staff training	Direct costs by health visitors (staff time), Travel Costs	Average monthly fee paid to the program per member				Nurse salary Overheads Subscription costs	Average monthly fee paid to the program per member
Comments	Participating site overheads were not measured, a "conservatively high" estimate of these was taken to double the treatment cost to USD 374	Costs of the health visitor also included time spent recording data collection for the study						Cost varied among the 15 included studies. Negotiated locally with Medicare and Medicaid Services. (Range USD 50 to USD 444)
Mean total healthcare costs per patient								
Total cost (intervention)	USD ~3300 (calc)	GBP 1801	USD 1627	USD 2356	USD 2288	USD 1793	USD 635	USD 1283*
Total cost (control)	USD ~6500	GBP 1812	USD 1632	USD 2464	USD 2372	USD 1818	USD 2053	USD 1314*

Table 18. Cost summary of intervention and comparison of healthcare costs incurred by intervention and control groups during follow-up period (*Continued*)

Between group difference	USD ~1800*	GBP 9.60	USD 5	USD 107	USD 84	USD 25	USD 1418	USD 144 (80% CI 99 to 188)
P value	NR	NS	0.895	0.077	0.132	0.365	NR	< 0.001
Cost saving per pt (when cost of intervention taken into account§)	USD ~1610 or USD ~1420 if estimated overheads were included	GBP 40	USD -157	USD -55	USD -78	USD -137	USD 965	USD -52
Additional healthcare costs considered	Number of admissions (heart related), number of inpatient days, In patient cost' emergency department costs	Prescription of drugs, GP visits, visits to hospital as inpatients and outpatients, all tests investigations and treatments carried out	Medicare medical claims				Cardiovascular-related emergency department visits and hospitalisations	
Comments	Expenditure was calculated from differences in % utilisation of hospital services. i.e. hospital charges for participants were on average 49% lower and the average annual expenditure was USD 6500 * There was a calcu-	There was a difference in the drug usage at baseline which is not accounted for in these figures although this would make minimal impact to the results. The intervention group were more costly for drugs, procedures and service use	Claims quoted are per member per month					*Expenditure/ pt/month enrolled Overall costs were increased by 11% when the care coordination fees were taken into account

Table 18. Cost summary of intervention and comparison of healthcare costs incurred by intervention and control groups during follow-up period (*Continued*)

	lated saving of a hospital charge of USD 3200, the ratio of payments to charges was 0. 56 therefore USD 1800 actual saving				
Summary difference between groups	**Favours Rx**	Rx = Control	Rx = control (for all time periods studied)	**Favours Rx**	**Favours control**

§ = Negative mean difference indicates a net cost of the intervention group
NR = not recorded
NS = not significant

Table 19. Results of univariate meta-regression analysis for total mortality

Explanatory variable (n trials)	Exp(slope)*	95% CI univariate; P value	Proportion of variation explained	Interpretation
Case mix (% myocardial infarction patients) (n = 11)	RR = 1.004	0.988 to 1.020 P = 0.631	-190.36%	No evidence that RR is associated with case mix
Age of participants (n = 13)	RR = 1.005	0.940 to 1.074 P = 0.876	-28.26%	No evidence that RR is associated with the age of participants
Percentage of male participants (n = 13)	RR = 0.991	0.986 to 1.012 P = 0.882	-25.27%	No evidence that RR is associated with the percentage of male participants
Type of CR (education only vs. education plus e. g. exercise or psychological intervention) (n = 13)	RR = 0.181	0.014 to 2.321 P = 0.168	28.25%	No evidence that RR is associated with type of CR
Method of structured ed- ucational delivery (one-to-one vs. group versus	RR = 1.010	0.728 to 1.401 P = 0.948	-28.28%	No evidence that RR is associated with method of delivery

Table 19. Results of univariate meta-regression analysis for total mortality (*Continued*)

combination) (n = 13)				
Duration of intervention (n = 12)	RR = 0.978	0.948 to 1.010 P = 0.152	3.69%	No evidence that RR is associated with duration of intervention
Theoretical vs. no theoretical basis to educational intervention (n = 13)	RR = 1.473	0.750 to 2.895 P = 0.233	-0.31%	No evidence that RR is associated with theoretical basis
Involvement of significant others (e.g. spouse, family member) in the education programme (n = 13)	RR = 1.245	0.890 to 1.722 P = 0.166	7.06%	No evidence that RR is associated with family involvement
Study location (n = 13)	RR = 1.050	0.714 to 1.543 P = 0.787	-59.78%	No evidence that risk ratio is associated with study location
Setting (centre vs. home) (n = 13)	RR = 1.171	0.773 to 1.774 P = 0.421	-44.55%	No evidence that RR is associated with centre status
Length of follow-up (n = 13)	RR = 0998	0.964 to 1.033 P = 0.924	-22.64%	No evidence that RR is associated with length of follow-up

CR - cardiac rehabilitation; RR - risk ratio

Table 20. Results of univariate meta-regression analysis for withdrawal

Explanatory variable (n trials)	Exp(slope)*	95% CI univariate P value	Proportion of variation explained	Interpretation
Case mix (% myocardial infarction patients) (n = 12)	RR = 1.002	0.992 to 1.013 P = 0.611	-9.25%	No evidence that RR is associated with case mix
Age of participants (n = 17)	RR = 0.998	0.963 to 1.034 P = 0.903	-15.62%	No evidence that RR is associated with the age of participants
Percentage of male participants (n = 17)	RR = 0.999	0.992 to 1.005 P = 0.621	-28.64%	No evidence that RR is associated with the percentage of male participants

Table 20. Results of univariate meta-regression analysis for withdrawal (*Continued*)

Type of CR (education only vs. education plus e. g. exercise or psychological intervention) (n = 17)	RR = 0.752	0.260 to 2.174 P = 0.575	-16.99%	No evidence that RR is associated with type of CR
Method of structured ed- ucational delivery (one-to-one vs. group versus combination) (n = 17)	RR = 1.033	0.860 to 1.242 P = 0.714	-29.18%	No evidence that mortality risk is associated with method of delivery
Duration of intervention (n = 16)	RR = 0.993	0.964 to 1.023 P = 0.625	-25.06%	No evidence that mortality risk is associated with duration of intervention
Theoretical vs. no theoretical basis to educational intervention (n = 17)	RR = 1.031	0.690 to 1.541 P = 0.874	-24.70%	No evidence that RR is associated with theoretical basis
Involvement of significant others (e.g. spouse, family member) in the education (n = 17)	RR = 1.016	0.829 to 1.245 P = 0.872	-33.62%	No evidence that RR is associated with family involvement
Study location (n = 17)	RR = 0.942	0.801 to 1.109 P = 0.449	24.47%	No evidence that RR is associated with study location
Setting (centre vs. home) (n = 17)	RR = 1.096	0.873 to 1.374 P = 0.404	-13.38%	No evidence that RR is associated with centre status
Length of follow-up (n = 17)	RR = 0 .976	0.955 to 0.998 P = 0.035	90.79%	Significant evidence that risk of withdrawal is increased in studies with a shorter follow-up

CR - cardiac rehabilitation; RR - risk ratio

Table 21. Results of sensitivity analysis for total mortality

Explanatory variable (n trials)	Exp(slope)*	95% CI univariate P value	Proportion of variation explained	Interpretation
Year of publication (n = 13)	RR = 0.998	0.950 to 1.047 P = 0.913	-61.7%	No evidence that RR is associated with year of publication

Table 21. Results of sensitivity analysis for total mortality (*Continued*)

Risk of bias (low risk in ≥ 5 items vs. < 5 items) (n = 13)	RR = 1.105	0.421 to 3.831 P = 2.899	-84.29%	No evidence that RR is associated with risk of bias

RR - risk ratio

Table 22. Results of sensitivity analysis for withdrawal

Explanatory variable (n trials)	Exp(slope)*	95% CI univariate P value	Proportion of variation explained	Interpretation
Year of publication (before 2000 vs. 2000 or later) (n = 17)	RR = 1.017	0.982 to 1.052 P = 0.327	-7.02%	No evidence that RR is associated with year of publication
Risk of bias (low risk in ≥ 5 items vs. < 5 items) (n = 17)	RR = 1.437	1.069 to 1.931 P = 0.020	15.35%	Significant evidence that risk of withdrawal is increased in studies with higher risk of bias

APPENDICES

Appendix 1. Search strategies

CENTRAL

#1 MeSH descriptor: [Myocardial Infarction] explode all trees
#2 myocardial infarct*:ti,ab,kw (Word variations have been searched)
#3 MeSH descriptor: [Angina Pectoris] explode all trees
#4 angina pectoris:ti,ab,kw (Word variations have been searched)
#5 angor pectoris:ti,ab,kw (Word variations have been searched)
#6 stenocardia*:ti,ab,kw (Word variations have been searched)
#7 coronary artery bypass*:ti,ab,kw (Word variations have been searched)
#8 CABG:ti,ab,kw (Word variations have been searched)
#9 aortocoronary bypass*:ti,ab,kw (Word variations have been searched)
#10 (coronary near/3 angioplast*):ti,ab,kw (Word variations have been searched)
#11 PTCA:ti,ab,kw (Word variations have been searched)
#12 (coronary near/2 dilatation*):ti,ab,kw (Word variations have been searched)
#13 MeSH descriptor: [Coronary Disease] explode all trees
#14 (coronary near/2 disease*):ti,ab,kw (Word variations have been searched)
#15 MeSH descriptor: [Myocardial Revascularization] explode all trees
#16 coronary artery stent*:ti,ab,kw (Word variations have been searched)
#17 MeSH descriptor: [Percutaneous Coronary Intervention] explode all trees
#18 (percutaneous coronary near/2 (interven* or revascular*)):ti,ab,kw (Word variations have been searched)
#19 MeSH descriptor: [Angioplasty] explode all trees

#20 angioplast*:ti,ab,kw (Word variations have been searched)
#21 ((coronary or arterial) near/4 dilat*):ti,ab,kw (Word variations have been searched)
#22 endoluminal repair*:ti,ab,kw (Word variations have been searched)
#23 MeSH descriptor: [Stents] explode all trees
#24 stent*:ti,ab,kw (Word variations have been searched)
#25 (pci or ptca):ti,ab,kw (Word variations have been searched)
#26 Atherectomy:ti,ab,kw (Word variations have been searched)
#27 atherectom*:ti,ab,kw (Word variations have been searched)
#28 acute coronary syndrom*:ti,ab,kw (Word variations have been searched)
#29 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28
#30 MeSH descriptor: [Patient Education as Topic] this term only
#31 MeSH descriptor: [Health Education] this term only
#32 MeSH descriptor: [Telemedicine] this term only
#33 (patient* near/6 (educat* or communicat* or interacti* or inform* or advi*)):ti,ab,kw (Word variations have been searched)
#34 (educat* near/6 (intervention* or rehabilation* or program*)):ti,ab,kw (Word variations have been searched)
#35 (education near/6 (service* or group* or program* or session*)):ti,ab,kw (Word variations have been searched)
#36 (education near/6 prevent*):ti,ab,kw (Word variations have been searched)
#37 ((rehabilitati* or educat*) near/6 (literature or audiovisual or av or audio visual or internet or web* or telecare or telemedicine or telephone* or phone* or teleconference* or telehealth or transtelephonic* or podcast* or email* or e-mail*)):ti,ab,kw (Word variations have been searched)
#38 ((educat* or intervent*) near/6 (communit* or famil* or spouse* or nurs*)):ti,ab,kw (Word variations have been searched)
#39 #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38
#40 #29 and #39 Publication Year from 2010 to 2016

MEDLINE

1 exp Myocardial Infarction/ (153085)
2 myocardial infarct*.tw. (146020)
3 exp Angina Pectoris/ (48551)
4 angina pectoris.tw. (16788)
5 angor pectoris.tw. (37)
6 stenocardia*.tw. (929)
7 coronary artery bypass*.tw. (30408)
8 CABG.tw. (12609)
9 aortocoronary bypass*.tw. (2354)
10 (coronary adj3 angioplast*).tw. (13556)
11 PTCA.tw. (6101)
12 (coronary adj2 dilatation*).tw. (565)
13 exp Coronary Disease/ (189971)
14 (coronary adj2 disease*).tw. (108936)
15 exp Myocardial Revascularization/ (82266)
16 coronary artery stent*.tw. (870)
17 exp Percutaneous Coronary Intervention/ (38918)
18 (percutaneous coronary adj2 (interven* or revascular*)).tw. (17683)
19 exp Angioplasty/ (56065)
20 angioplast*.tw. (36109)
21 ((coronary or arterial) adj4 dilat*).tw. (4567)
22 endoluminal repair*.tw. (207)
23 exp Stents/ (57098)
24 stent*.tw. (63468)
25 (pci or ptca).tw. (19345)
26 exp Atherectomy/ (2017)
27 atherectom*.tw. (2227)
28 acute coronary syndrom*.tw. (18048)

29 or/1-28 (503551)
30 Patient Education as Topic/ (72978)
31 Health Education/ (53706)
32 Telemedicine/ (12531)
33 (patient* adj6 (educat* or communicat* or interacti* or inform* or advi*)).tw. (133035)
34 (educat* adj6 (intervention* or rehabilation* or program*)).tw. (54507)
35 (education adj6 (service* or group* or program* or session*)).tw. (43822)
36 (education adj6 prevent*).tw. (7681)
37 ((rehabilitati* or educat*) adj6 (literature or audiovisual or av or audio visual or internet or web* or telecare or telemedicine or telephone* or phone* or teleconference* or telehealth or transtelephonic* or podcast* or email* or e-mail*)).tw. (6087)
38 ((educat* or intervent*) adj6 (communit* or famil* or spouse* or nurs*)).tw. (71758)
39 or/30-38 (354368)
40 randomized controlled trial.pt. (404415)
41 controlled clinical trial.pt. (91176)
42 randomized.ab. (297250)
43 placebo.ab. (155316)
44 drug therapy.fs. (1811236)
45 randomly.ab. (210643)
46 trial.ab. (308679)
47 groups.ab. (1332430)
48 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 (3410956)
49 exp animals/ not humans.sh. (4078149)
50 48 not 49 (2906978)
51 29 and 39 and 50 (3534)
52 (20108* or 201009* or 201010* or 201011* or 201012* or 2011* or 2012* or 2013* or 2014* or 2015* or 2016*).ed. (3869988)
53 51 and 52 (804)

Embase

1 exp Myocardial Infarction/ (281562)
2 myocardial infarct*.tw. (199379)
3 exp Angina Pectoris/ (78516)
4 angina pectoris.tw. (20262)
5 angor pectoris.tw. (54)
6 stenocardia*.tw. (836)
7 coronary artery bypass*.tw. (40577)
8 CABG.tw. (22875)
9 aortocoronary bypass*.tw. (2231)
10 (coronary adj3 angioplast*).tw. (16678)
11 PTCA.tw. (7865)
12 (coronary adj2 dilatation*).tw. (725)
13 exp Coronary Disease/ (239803)
14 (coronary adj2 disease*).tw. (154969)
15 exp Myocardial Revascularization/ (23708)
16 coronary artery stent*.tw. (1348)
17 exp Percutaneous Coronary Intervention/ (67150)
18 (percutaneous coronary adj2 (interven* or revascular*)).tw. (33814)
19 exp Angioplasty/ (70172)
20 angioplast*.tw. (49254)
21 ((coronary or arterial) adj4 dilat*).tw. (5705)
22 endoluminal repair*.tw. (245)
23 exp Stents/ (114572)
24 stent*.tw. (109268)
25 (pci or ptca).tw. (40833)
26 exp Atherectomy/ (3792)

27 atherectom*.tw. (3109)
28 acute coronary syndrom*.tw. (33277)
29 or/1-28 (720658)
30 Patient Education as Topic/ (91427)
31 Health Education/ (79681)
32 Telemedicine/ (13152)
33 (patient* adj6 (educat* or communicat* or interacti* or inform* or advi*)).tw. (218886)
34 (educat* adj6 (intervention* or rehabilation* or program*)).tw. (75754)
35 (education adj6 (service* or group* or program* or session*)).tw. (60070)
36 (education adj6 prevent*).tw. (10354)
37 ((rehabilitati* or educat*) adj6 (literature or audiovisual or av or audio visual or internet or web* or telecare or telemedicine or telephone* or phone* or teleconference* or telehealth or transtelephonic* or podcast* or email* or e-mail*)).tw. (9451)
38 ((educat* or intervent*) adj6 (communit* or famil* or spouse* or nurs*)).tw. (90582)
39 or/30-38 (505428)
40 random$.tw. (986880)
41 factorial$.tw. (25324)
42 crossover$.tw. (52424)
43 cross over$.tw. (23038)
44 cross-over$.tw. (23038)
45 placebo$.tw. (216471)
46 (doubl$ adj blind$).tw. (152174)
47 (singl$ adj blind$).tw. (15997)
48 assign$.tw. (263111)
49 allocat$.tw. (94003)
50 volunteer$.tw. (189353)
51 crossover procedure/ (43468)
52 double blind procedure/ (121614)
53 randomized controlled trial/ (376146)
54 single blind procedure/ (20516)
55 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 (1555250)
56 (animal/ or nonhuman/) not human/ (4831248)
57 55 not 56 (1374700)
58 29 and 39 and 57 (2796)
59 (20108* or 201009* or 201010* or 201011* or 201012* or 2011* or 2012* or 2013* or 2014* or 2015* or 2016*).dd. (7210311)
60 58 and 59 (1249)
61 limit 60 to embase (1113)

PsycINFO

1 exp Myocardial Infarction/ (2478)
2 myocardial infarct*.tw. (3655)
3 exp Angina Pectoris/ (274)
4 angina pectoris.tw. (331)
5 angor pectoris.tw. (0)
6 stenocardia*.tw. (8)
7 coronary artery bypass*.tw. (740)
8 CABG.tw. (375)
9 aortocoronary bypass*.tw. (8)
10 (coronary adj3 angioplast*).tw. (106)
11 PTCA.tw. (51)
12 (coronary adj2 dilatation*).tw. (2)
13 (coronary adj2 disease*).tw. (5470)
14 coronary artery stent*.tw. (3)
15 (percutaneous coronary adj2 (interven* or revascular*)).tw. (146)
16 angioplast*.tw. (299)

17 ((coronary or arterial) adj4 dilat*).tw. (46)
18 endoluminal repair*.tw. (0)
19 exp Stents/ (0)
20 stent*.tw. (370)
21 (pci or ptca).tw. (499)
22 exp Atherectomy/ (0)
23 atherectom*.tw. (0)
24 acute coronary syndrom*.tw. (410)
25 Health Education/ (10509)
26 Telemedicine/ (2882)
27 (patient* adj6 (educat* or communicat* or interacti* or inform* or advi*)).tw. (38816)
28 (educat* adj6 (intervention* or rehabilation* or program*)).tw. (51901)
29 (education adj6 (service* or group* or program* or session*)).tw. (43021)
30 (education adj6 prevent*).tw. (4319)
31 ((rehabilitati* or educat*) adj6 (literature or audiovisual or av or audio visual or internet or web* or telecare or telemedicine or telephone* or phone* or teleconference* or telehealth or transtelephonic* or podcast* or email* or e-mail*)).tw. (8262)
32 ((educat* or intervent*) adj6 (communit* or famil* or spouse* or nurs*)).tw. (54258)
33 or/25-32 (161409)
34 or/1-24 (10643)
35 random$.tw. (144014)
36 factorial$.tw. (15416)
37 crossover$.tw. (5725)
38 cross-over$.tw. (2130)
39 placebo$.tw. (33120)
40 (doubl$ adj blind$).tw. (19491)
41 (singl$ adj blind$).tw. (1662)
42 assign$.tw. (75187)
43 allocat$.tw. (22136)
44 volunteer$.tw. (31178)
45 control*.tw. (528436)
46 ”2000“.md. (30342)
47 or/35-46 (712946)
48 33 and 34 and 47 (297)
49 limit 48 to yr=”2010 -Current“ (102)

CINAHL

S58 S40 AND S57 Limiters - Published Date: 20100801-20160510
S57 S41 or S42 or S43 or S44 or S45 or S46 or S47 or S48 or S49 or S50 or S51 or S52 or S53 or S54 or S55 or S56 or S57
S56 TX cross-over*
S55 TX crossover*
S54 TX volunteer*
S53 (MH ”Crossover Design“)
S52 TX allocat*
S51 TX control*
S50 TX assign*
S49 (MH ”Placebos“)
S48 TX random*
S47 TX (doubl* N1 mask*)
S46 TX (singl* N1 mask*)
S45 TX (doubl* N1 blind*)
S44 TX (singl* N1 blind*)
S43 TX (clinic* N1 trial?)
S42 PT clinical trial
S41 (MH ”Clinical Trials+“)

S40 S29 AND S39
S39 S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38
S38 ((educat* or intervent*) N6 (communit* or famil* or spouse* or nurs*))
S37 ((rehabilitati* or educat*) N6 (literature or audiovisual or av or audio visual or internet or web* or telecare or telemedicine or telephone* or phone* or teleconference* or telehealth or transtelephonic* or podcast* or email* or e-mail*))
S36 (education N6 prevent*)
S35 (education N6 (service* or group* or program* or session*))
S34 (educat* N6 (intervention* or rehabilation* or program*))
S33 (patient* N6 (educat* or communicat* or interacti* or inform* or advi*)) Search modes - Boolean/Phrase Interface - EBSCOhost
S32 (MH "Telemedicine")
S31 (MH "Health Education+")
S30 (MH "Patient Education")
S29 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28
S28 acute coronary syndrom*
S27 atherectom*
S26 (MH "Atherectomy+")
S25 (pci or ptca)
S24 stent*
S23 (MH "Stents+")
S22 endoluminal repair*
S21 ((coronary or arterial) N4 dilat*)
S20 angioplast*
S19 (MH "Angioplasty+")
S18 (percutaneous coronary N2 (interven* or revascular*))
S17 (MH "Angioplasty, Transluminal, Percutaneous Coronary")
S16 coronary artery stent*
S15 (MH "Myocardial Revascularization+")
S14 (coronary N2 disease*)
S13 (MH "Coronary Disease+")
S12 (coronary N2 dilatation*)
S11 PTCA
S10 (coronary N3 angioplast*)
S9 aortocoronary bypass*
S8 CABG
S7 coronary artery bypass*
S6 stenocardia*
S5 angor pectoris
S4 angina pectoris
S3 (MH "Angina Pectoris+")
S2 myocardial infarct*
S1 (MH "Myocardial Infarction+")

WHO ICTRP

"education" AND "coronary artery disease" OR "education" AND "coronary heart disease"

Clinicaltrials.gov

"education" AND "coronary artery disease" OR "education" AND "coronary heart disease"

UK Clinical Trials Gateway

”education“ AND ”coronary artery disease“ OR ”education“ AND ”coronary heart disease“

WHAT'S NEW

Last assessed as up-to-date: 30 June 2016.

Date	Event	Description
12 October 2016	New citation required but conclusions have not changed	An additional 9 new RCTs (8215 participants) have been added in this update
30 June 2016	New search has been performed	The searches were re-run on 30 June 2016 and the results from this new search were subsequently incorporated into the review

CONTRIBUTIONS OF AUTHORS

LA undertook the study selection, data extraction and risk of bias assessment, and led the writing of the updated review.

JPRB led the writing of the original version of the review and contributed to the editing of the updated review.

AMC contributed to the original version of the review and contributed to the editing of the updated review.

HD contributed to the original version of the review and contributed to the editing of the updated review.

HKR undertook data extraction and risk of bias assessment and contributed to the editing of the updated review.

CB conducted the searches.

RST contributed to the original version of the review, undertook study selection, data extraction, led the analysis of this review and contributed to the editing of the updated review.

The final manuscript was approved by all authors.

DECLARATIONS OF INTEREST

LA is an author on number of other Cochrane cardiac rehabilitation reviews.

RST is co-author on a number of Cochrane rehabilitation reviews and in receipt of two ongoing NIHR research grants in cardiac rehabilitation (PGfAR RP-PG-0611-12004; HTA 15/80/30 and one past (HTA 12/189/06).

JPRB, DH, AC, HKR and CB declare no conflicts of interest.

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- University of Exeter Medical School, UK.

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

To reflect current practice and terminology, "percutaneous transluminal coronary angioplasty" (PTCA) was replaced by "percutaneous coronary intervention" (PCI), a term which encompasses the use of balloons, stents, and atherectomy.

The list of primary and secondary outcomes was changed for clarity. The subheadings "Total cardiovascular events" and "Proportion of patients requiring admission in the follow-up period following the intervention" were deleted. Adverse events was added as a secondary outcome measure to comply with Methodological Expectations of Cochrane Intervention Reviews (MECIR) Standards (MECIR 2016). Where reported, adverse events were extracted from all studies included in this update.

In the protocol we stated that we planned to use meta-regression and stratified meta-analyses to explore heterogeneity and to compare and investigate the different modalities of education delivery and to investigate particular subgroups of coronary heart disease (CHD) patients. However, as outlined in this review, there were insufficient data to undertake these analyses for any outcomes other than total mortality and withdrawal. We examined the effect of all predefined potential treatment effect modifiers on these outcomes, with the exception of timing after index event, which was poorly reported in the study reports.

We created a 'Summary of findings' table using the following outcomes: total mortality, fatal and/or non fatal myocardial infarction (MI), other fatal and/or non-fatal cardiovascular events, total revascularisations, hospitalisations, withdrawals and health-related quality of life (HRQoL).

We added a post-hoc sensitivity analysis by statistical model (mixed- versus fixed-effects). Although we reported results of the random-effects modelling in the text, we also reported the results of both models for all outcomes (Table 1).

INDEX TERMS

Medical Subject Headings (MeSH)

*Coronary Disease [economics; mortality; rehabilitation]; *Health Care Costs; *Health Status; *Patient Education as Topic; *Quality of Life; Health Services Needs and Demand [utilization]; Myocardial Infarction [prevention & control]; Randomized Controlled Trials as Topic

MeSH check words

Adult; Humans; Middle Aged